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No.

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IN THE

Supreme Court of the United States

October Term 1984

GROCERY MANUFACTURERS OF AMERICA, INC.,
A Delaware Corporation,

Appellee,

v.

JOSEPH GERACE, Commissioner, New York Department of Agriculture and Markets, and THE NEW YORK DEPARTMENT OF AGRICULTURE AND MARKETS,

Appellants,

JOHN R. BLOCK, as Secretary of Agriculture of the United States and THE DEPARTMENT OF AGRICULTURE OF THE UNITED STATES, MARGARET M. HECKLER, as Secretary of Health and Human Services of the United States, and THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES,

Appellees.

On Appeal from the United States Court of Appeals for the Second Circuit

JURISDICTIONAL STATEMENT

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Questions Presented

1. Is New York Agriculture and Markets Law §63 unconstitutional under the Supremacy Clause because it requires that a food product which is made in semblance and simulation of another food must be labeled "imitation", whereas a Food and Drug Administration regulation [21 CFR §101.3(e)] requires such "imitation" labeling only if the imitation product is nutritionally inferior to the real food?

2. Does FDA's regulation violate the express imitation labeling provisions of the *Food, Drug and Cosmetic Act* [21 U.S.C. §343(e)] as construed by this Court in *62 Cases of Jam* v. *United States*, 340 U.S. 593 (1951) and *Federal Security Administration* v. *Quaker Oats*, 318 U.S. 218 (1943)?

3. Is judicial deference due to FDA's current construction of the statutory term "imitation", although it reverses the agency's own settled construction for over thirty years, and "is at odds with the judicial gloss placed on the term" (Opinion Below)?

4. Did the United States Department of Agriculture violate the Administrative Procedures Act (5 U.S.C. §552 and §553) by its attempt to adopt FDA's "Imitation" Regulation through the dicta of the agency's Judicial Officer in an administrative adjudication?

Parties

All parties to the proceeding in the courts below are listed in the caption of the case in this Court.

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GROCERY MANUFACTURERS OF AMERICA, INC., A Delaware Corporation,

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JOSEPH GERACE, Commissioner, New York Department of Agriculture and Markets, and THE NEW YORK DEPARTMENT OF AGRICULTURE AND MARKETS,

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Appellees.

On Appeal from the United States Court of Appeals for the Second Circuit

Jurisdictional Statement

Appellants Joseph Gerace, Commissioner of Agriculture and Markets of the State of New York, and the New York State Department of Agriculture and Markets, appeal from a judgment of the United States Court of Appeals for the

Second Circuit holding unconstitutional, under the Supremacy Clause, the labeling provisions of the New York Agriculture and Markets Law, §63, subd. 1 and subd. 2, and its accompanying regulations, governing the labeling of imitation cheese.

Opinions Below

The opinion of the United States Court of Appeals for the Second Circuit is reported at 755 F.2d 993 and is printed in the Appendix (*Infra,* p. 1a).

The opinion of the United States District Court for the Southern District of New York, which was reversed in part by the Court of Appeals, is reported at 581 F. Supp. 658 and is printed in the Appendix (*Infra,* p. 29a).

Jurisdiction

In 1983, appellee Grocery Manufacturers of America, filed a complaint in the United States District Court for the Southern District of New York alleging that New York Agriculture and Markets Law §63 and the regulations promulgated by the New York State Department of Agriculture and Markets under that statute concerning the labeling of imitation cheese (1 NYCRR Part 18) violated the Commerce Clause (Article I, Section 8, Clause 3), the Supremacy Clause, (Article VI, Clause 2), the Equal Protection Clause of the Fourteenth Amendment, and the Due Process Clause of the Fourteenth Amendment. Federal jurisdiction was invoked under 28 U.S.C. §1331 and §1343 and 42 U.S.C. §1983 and §1988. On March 6, 1983, the Dis-

tirct Court entered an order permanently enjoining the defendants from enforcing the New York statute and its implementing regulations upon the ground that they are preempted by federal regulations and that the menu and sign posting provisions place an unreasonable burden on interstate commerce.

On February 14, 1985, the United States Court of Appeals for the Second Circuit, in a final decision, affirmed that part of the decision of the District Court which found the labeling requirements of the New York statute and its implementing regulation unconstitutional under the Supremacy Clause, but reversed that part of the decision which invalidated, under the Commerce Clause, the sign, menu and container provisions of subdivisions 3, 4 and 5 of section 63 of the New York Agriculture and Markets Law as an unreasonable burden on interstate commerce.

The judgement of the Court of Appeals was entered on February 14, 1985. The Notice of Appeal was filed with the clerk of the Court of Appeals on May 3, 1985.

This Court has jurisdiction of this appeal pursuant to 28 U.S.C. §1254(2).

Constitutional, Statutory and Regulatory Provisions Involved

U.S. Constitution

ARTICLE VI, Clause 2:

> "This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Au-

thority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding."

New York Statute and Regulations

New York State Agriculture and Markets Law §63 and implementing regulations are set forth in their entirety in Appendix E and F. The critical provisions of each provide as follows:

Agriculture and Markets Law §63, subd. 1 and 2:

1. Whenever the brand name or product designation of imitation cheese or imitation cheese food appears on a package, the brand name or product designation, whichever is larger, shall be immediately preceded, without intervening printed or graphic material by the word imitation and the name of the food imitated, in letters of the same color and on the same contrasting background and of equal size as the brand name or product designation, whichever is larger.

2. On the label of any product containing imitation cheese or imitation cheese food, the product designation shall be immediately preceded or followed by the words "contains imitation cheese" or "contains imitation cheese food" whichever is appropriate, in letters of the same color and on the same contrasting background and of equal size as the product designation.

Title 1, Official Compilation of Codes, Rules and Regulations of the State of New York, Part 18:

Section 18.1 Definitions. As used in this Part, unless the context otherwise requires, the following terms shall have the following meanings:

* * *

(c) Imitation cheese means a food which is similar in texture, color, flavor, taste and appearance to a cheese, or a variety thereof, which is identified, described or defined in Part 17 of this Title, but does not meet a description, identity or definition for cheese as set forth therein.*

Federal Statutes and Regulations

The federal statutes involved in this case are the Food, Drug and Cosmetic Act (21 U.S.C. §341-343; §371); the Wholesome Meat Act (21 U.S.C. §601 and §678), the Poultry Products Inspection Act (21 U.S.C. §453 and §467e) and the Administrative Procedure Act (5 U.S.C. §552 and §553). The pertinent sections are set forth in Appendix G through K, *infra.*

Of all the statutes and regulations involved, the critical provisions are:

Food, Drug and Cosmetic Act

21 U.S.C. §343

A food shall be deemed to be misbranded—

* * *

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence,

* Part 17, to which the regulation refers, contains definition and standards of identity for various types of cheese.

the word "imitation" and, immediately thereafter, the name of the food imitated.

* * *

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not promiently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purportes to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401 [21 USCS §341] unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring)

21 U.S.C. §342

A food shall be deemed to be adulterated—

* * *

(b)(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

FDA's Imitation Regulation

21 CFR §101.3(e)

(e) Under the provisions of section 403(c) of the Federal Food, Drug and Cosmetic Act, a food shall be deemed to be misbranded if it is an imitation of another food unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(1) A food shall be deemed to be an imitation and thus subject to the requirements of section 403(c) of the act if it is a substitute for and resembles another food but is nutritionally inferior to that food.

(2) A food that is a substitute for and resembles another food shall not be deemed to be an imitation provided it meets each of the following requirements:

(i) It is not nutritionally inferior to the food for which it substitutes and which it resembles.

(ii) Its label bears a common or usual name that complies with the provisions of §102.5 of this chapter and that is not false or misleading, or in the absence of an existing common or usual name, an appropriately descriptive term that is not false or misleading. The label may, in addition, bear a fanciful name which is not false or misleading.

(3) A food for which a common or usual name is established by regulation (e.g., in a standard of identity pursuant to section 401 of the act, in a common or usual name regulation pursuant to Part 102 of this chapter, or in a regulation establishing a nutritional quality guideline pursuant to Part 104 of this chapter), and which complies with all of the applicable requirements of such regulation(s), shall not be deemed to be an imitation.

(4) Nutritional inferiority includes:

(i) Any reduction in the content of an essential nutrient that is present in a measurable amount, but does not include a reduction in the caloric or fat content provided the food is labeled pursuant to the provisions of §101.9, and provided the labeling with respect to any reduction in caloric content complies with the provisions applicable to caloric content in Part 105 of this chapter.

(ii) For the purpose of this section, a measurable amount of an essential nutrient in a food shall be considered to be 2 percent or more of the U.S. RDA of protein or any vitamin or mineral listed under §101.9 (c)(7)(iv) of this chapter per average or usual serving, or where the food is customarily not consumed directly, per average or usual portion, as established in §101.9.

(iii) If the Commissioner concludes that a food is a substitute for and resembles another food but is inferior to the food imitated for reasons other than those set forth in the paragraph, he may propose appropriate revisions to this regulation or he may propose a separate regulation governing the particular food.

Statement of the Case

A. The Proceedings Below

Grocery Manufacturers of America, Inc., ("GMA"), a trade association, filed a complaint in the United States District Court (S.D.N.Y.) seeking to enjoin the New York State Department of Agriculture and Markets and Joseph Gerace, Commissioner of the Department ("New York") from enforcing a recently enacted statute, New York Agri-

culture and Markets Law §63 and its implementing regulations, (1 NYCRR Part 18). The New York law governs labeling and other forms of consumer disclosure with respect to imitation cheese. GMA alleged that existing federal statutes and regulations addressed to the labeling of imitation foods conflict with and preempt, the New York law. GMA also attacked the New York law under the Commerce Clause.

New York answered and filed a counterclaim. New York alleged that there was no irreconcilable conflict between New York law and federal regulations, but also alleged that the Food and Drug Administration regulation governing the labeling of imitation foods (21 CFR §101.3) was invalid and in violation of the Food, Drug and Cosmetic Act (21 U.S.C. §343). New York also attacked the validity, under the Administrative Procedures Act (5 U.S.C. §552 et seq.), of the United States Department of Agriculture's adoption of the Food and Drug regulation. The counterclaim named as additional defendants the United States Department of Agriculture ("USDA"), the United States Department of Health and Human Services, the parent agency of the Food and Drug Administration ("FDA"), and the Secretaries of those Departments.

The District Court (Kevin Thomas Duffy, J.), in a decision reported at 581 F. Supp. 658 (S.D.N.Y. 1984), enjoined the enforcement of N.Y. Agriculture and Markets Law §63 and its enabling regulation, under both the Supremacy Clause and the Commerce Clause. On appeal, the United States Court of Appeals for the Second Circuit affirmed that part of the District Court's decision which

held the New York statute and regulations unconstitutional under the Supremacy Clause but reversed with respect to the District Court's holding that the sign, menu and container provisions were in conflict with the Commerce Clause.

The Supremacy Clause issue, explicitly raised in the complaint and answer, has been presented and passed upon at each stage of the litigation.

B. The Challenged New York Statute and Regulations

New York's general counterpart to the Federal Food, Drug and Cosmetic Act has, for the 45 years since its enactment, provided (in language identical to the federal act) that any food which is in imitation of another food is misbranded "unless the label bears, in type of uniform size and prominence, the word 'imitation' and, immediately thereafter the name of the food imitated." (N.Y. Agriculture and Markets Law §202, subd. 3)

Agriculture and Markets Law §63 merely applies this general rue specifically to imitation cheese. It requires that imitation cheese must bear the word "imitation" preceding the product name on the label. It also requires that products which *contain* imitation cheese must be so labeled. Restaurants and fast-food establishments which use imitation cheese must so notify consumers by sign and menu disclosure.

New York's implementing regulations define the words "imitation cheese" to mean a food "which is similar in texture, color, flavor, taste and appearance to a cheese, or a

variety thereof, which is identified, described or defined in Part 17 of this Title, but does not meet a description, identity or definition for cheese as set forth therein.'"*

The New York regulations ascribe the plain and ordinary meaning to the word "imitation", because that is the way New York has consistently and successfully construed the term in its general food labeling statute. See *Swift & Company, Inc.* v. *Walkley,* 369 F. Supp. 1198 (S.D.N.Y. 1973) (WIENFELD, J.); *Dyson* v. *Miles Laboratories,* 57 A.D. 2d 197 (3d Dept. 1977)

C. The Chemistry and Economics of Imitation Cheese

The major difference between authentic, natural cheese and imitation cheese is the protein and fat used in their manufacture. The basic ingredient of almost all natural cheese is milk. In the manufacture of imitation cheese, vegetable oils and casein are substituted for milk. All are significantly cheaper in cost than the natural dairy butterfat for which they substitute. The opinion of the Court of Appeals notes the imitation product "sells at prices fifty to sixty percent lower than real cheese." (Appendix, *infra.*) This apparently refers to wholesale prices since *retail* prices reflect no such advantage. (Graf, *Economic Impact of Imitation Cheese,* Joint App. p. 155)

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* This is a reference to New York's standards of identity for over 70 types of cheese. (1 NYCRR §17.29-§17.102). New York's identity standards are identical to those adopted by the Food and Drug Administration (21 CFR §133.102-§133.196), except that New York has adopted additional standards for products not defined by FDA, such as ricotta cheese. New York has also adopted by reference, and in general, all of FDA's standards (1 NYCRR §250.1). Therefore, any standards for new types of cheese which might be adopted by FDA would become New York's standard as well.

There are two basic ways to manufacture imitation cheese. An industry chemist testified at the state rulemaking hearing:

> One alternative is to take milk and remove the butterfat from the milk by separation. And you wind up with skim milk. And then you add back to that a vegetable oil by hydrogenated soybean oil or corn oil. And then you make cheese out of it." (JA 152-153)

The abstracted butterfat is then available to manufacture a variety of other foods—cream cheese, ice cream, butter.*

The imitation product can also be manufactured directly from a formula by mixing and heating the various chemical constituents. The ingredient listing on a pizza label made with imitation cheese (introduced at the state rulemaking hearing) reveals that the "cheese" content consists of the following chemicals:

> "cheeses (low moisture part-skim milk mozzarella substitute [water, casein, partially hydrogenated soybean oil, salt, sodium, aluminum phosphate, lactic acid, natural flavor, starch, sodium citrate, sorbic acid (preservative), trisodium phosphate, artificial color, guar gum, artificial flavor, magnesium oxide, ferric orthophosphate, zinc oxide, riboflavin, cyancobalamin, folic acid, pyridoxine HCL (vitamin B-6), niacinamide, thiamin mononitrate, vitamin A palmitate], low moisture part-skim mozzarella)." (JA 129)

USDA allows manufacturers to dilute the cheese content in pizza with imitation cheese by a 9:1 ratio without any warning on the product label. (Joint App. 132)

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* 21 U.S.C. §342 provides in part that:

"A food shall be deemed to be adulterated * * * (b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom * * *"

D. Federal Statutes and Regulations

Food labeling at the federal level is governed in general by the Food, Drug and Cosmetic Act (FDCA) (21 U.S.C. §301 *et seq.*) Pizza, which contain both cheese and meat (and other cheese products with a meat constituent) are subject to federal meat inspection and are therefore subject to the Federal Meat Inspection Act (FMIA) (21 U.S.C. §601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. §451). The imitation labeling provisions of the FMIA and PPIA replicate the imitation provisions of FDCA verbatim, and derive directly from it.

The Food & Drug Act of 1938 addresses both the authenticity of foods and the imitation of foods in several interrelated sections:

The authenticity of foods is addressed by 21 U.S.C. §371-e, which authorizes FDA to establish definitions and standards of identity for foods. FDA has established standards for over 70 different types of cheese. All require the use of dairy ingredients. (21 CFR §133.102-133.196)*

Under 21 U.S.C. §343(g) a food is misbranded if it purports to be a food for which a standard of identity has been prescribed, such as cheese, and it does not conform to the standard. Under 21 U.S.C. a food is misbranded,

> "If it is in imitation of another food, unless its label bears, in type of uniform size and prominence, the word 'imitation' and, immediately thereafter, the name of the food imitated."

* They are identical with New York's, *supra* p.10.

A counterpart provision of 21 U.S.C. §342 defines as "adulterated" as food for which "any valuable constituent has been in whole or in part omitted."

The FDA's original and long-standing administrative construction of the statute accorded to the word "imitation" its ordinary meaning. FDA has acknowledged:

> "Before 1973, 'imitation' had to appear on the label of all substitute foods except for the few that went through the process of obtaining a new standard of identity for common or usual name. This policy did not directly take into account nutrient content." [*Advanced Notice of Proposed Rulemaking,* Dec. 21, 1978, 44 Fed. Reg. 76008. See also 43 Fed. Reg. 25304]

In 1967 Congress adopted the Wholesome Meat Act (21 U.S.C. §601 *et seq.*) Among other things, it adopted verbatim the definitions of "adulterated" and "misbranded" and the provisions relating to "imitation" food of the Food, Drug and Cosmetic Act. It is clear that Congress intended to conform the Meat Inspection Act to the labeling criteria then applicable under the Food, Drug and Cosmetic Act. (Senate Report No. 799, Nov. 21, 1967; 2 U.S. Code, Cong. & Admin. News [1967], 2188 2202-03)

In 1968, Congress adopted the Poultry Products Inspection Act (P.L. 90-492, 82 Stat. 791). This statute added to 21 U.S.C. §453(h) the same definition of misbranding and the same "imitation" provisions, with the expressed intention to conform to the Meat Inspection Act (House Agriculture Committee Report No. 1333, April 30, 1968; 3 U.S. Code, Cong. and Admin. News [1968], 3426, 3445)

In 1969 the White House Conference on Food, Nutrition and Health recommended *legislation to amend* the

imitation labeling provisions of federal law. (*White House Conf. Report,* p. 120, 127-128, 275)

Without benefit of legislation, FDA promulgated its new Imitation Regulation on August 2, 1973. It restricts the term "imitation" to products which are nutritionally inferior to the authentic food (21 CFR §101.3(e)(1). Nutritional inferiority is detemined by comparing the percentages of protein and nineteen vitamins and minerals set forth in 21 CFR §101.9(c)(7)(iv).

The language of the FDA regulation *authorizes* a nutritionally equivalent product to be marketed without an imitation label. The regulation does not, on its face, *prohibit* the labeling of such product as an "imitation". In fact, FDA's promulgating preamble states:

> "A manufacturer or distributor may label a substitute food which is not nutritionally inferior to the traditional food as an imitation if *he concludes* that the product is inferior in some other way and if the use of the term is not misleading." [38 Fed. Reg. 10703] (Emphasis added)

However, FDA accords that option only to the manufacturer or distributor. FDA refuses to allow the use of the "imitation" label in order to comply with state law.

Since 1973 when FDA adopted the new definition, New York has challenged the labeling of any foods sold in New York which were labeled in accordance with the new definition. *Swift* v. *Walkley,* 369 F. Supp. 1198 (S.D.N.Y. 1973) (WIENFELD, J.); *Dyson* v. *Miles Laboratories, Inc.,* 57 A.D. 2d 197 (3d Dept. 1977).

USDA has never adopted a regulation giving a new meaning to the term "imitation". On September 18, 1981,

USDA's Judicial Officer rendered on opinion *In re Castleberry Food Co.* (40 Agricultural Decisions 1262) in a proceeding involving a product in imitation of Corned Beef Hash. He expressly found that the product was nutritionally inferior. (40, A.D. at 1270, Finding 6) Nevertheless, he made an additional finding, upon testimony of Department witnesses, that USDA's practice was to follow the FDA regulation—although the witnesses could not say when USDA began the practice. The Judicial Officer also found that even if USDA had no policy,

> "I would have to determine the policy to be followed in this case and in future cases . . . and my determination would be to follow the Food and Drug Administration's policy as to nutritional inferiority." (40 A.D. 1262, 1278 f.n.7)

The Judicial Officer's delegated power did not include adoption of agency rules (7 CFR §2.35). The issue under adjudication did not require the formulation of agency policy on nutritionally equivalent imitations because the product was nutritionally inferior. (40 A.D. 1270)

THE QUESTIONS PRESENTED REQUIRE PLENARY CONSIDERATION BECAUSE THEY ARE SUBSTANTIAL AND HAVE A NATIONWIDE IMPACT.

I. The Questions Are Substantial

(1)

The Court of Appeals recognized that a substantial question is presented by New York's challenge to the validity of FDA's Imitation Regulation:

> "New York correctly notes that the FDA's regulatory definition of imitation is at odds with the judicial gloss

> placed on the term. Consequently, the state avers, we should disregard the definition and follow the reasoning of *Swift & Co.* v. *Walkley,* 369 F.Supp. 1198 (S.D.N.Y. 1973), decided under the FMIA."

Judge WIENFELD's opinion in *Swift & Co.* v. *Walkley, supra.* followed "the judicial gloss placed upon the term" by this Court. This Court's holding in *62 Cases of Jam* v. *United States,* 340 U.S. 593 (1951) is succinctly stated in the opinion:

> "Imitation foods are dealt with in §403(c) of the Act. In that section Congress did not give an esoteric meaning to 'imitation'. It left it to the understanding of ordinary English speech. And it directed that a product should be deemed 'misbranded' if it imitated another food 'unless its label bears, in type of uniform size and prominence, the word "imitation" and immediately thereafter, the name of the food imitated.'
>
> In ordinary speech there can be no doubt that the product which the United States here seeks to condemn is an 'imitation' jam. It looks and tastes like jam . . ." (340 U.S. at 599)

This Court referred to the imitation product as "a different, an inferior preserve, not meeting the defined specifications". (340 U.S. at 600) This reference to "inferiority" necessarily must be to economic, not nutritional, inferiority. The opinion cites Senate Rep. No. 361, 74th Cong., 1st Sess. 8-11. The cited report demonstrates that Congress was concerned with " 'economic adulteration,' that is, the cheapening of foods either through lessening the quantities of valuable constituents or through the substitution of cheaper constituents * * *" (*Id.* p. 10)

The FDA regulation subverts this legislative purpose to prevent economic adulteration.

Federal Security Administrator v. *Quaker Oats,* 318 U.S. 218 (1943), decided less than five years after the 1938 Act became effective, established that the purpose of the Food and Drug Act of 1938 was to protect the consumer from *economic* adulteration. (318 U.S. at 230) A substantial portion of the Quaker Oats opinion is devoted to an anlysis of the text and legislative history of the 1938 Act. This Court concluded:

> "Both the text and legislative history of the present statute plainly show that its purpose was not confined to a requirement of truthful and informative labeling. False and misleading labeling had been prohibited by the Pure Food and Drug Act of 1906. But it was found that such a prohibition was inadequate to protect the consumer from *'economic adulteration,' by which less expensive ingredients were substituted,* or the proportion of more expensive ingrendients diminished, so as *to make the product,* although not in itself deleterious, *inferior* to that which the consumer expected to receive when purchasing a product with the name under which it was sold. Sen. Rep. No. 493, 73rd Cong., 2d Sess., p. 10; Sen. Rep. No. 361, 74th Cong., 1st Sess., p. 10." (Emphasis Added.) (318 U.S. at 230)

See also *United States* v. *216 Cartons,* 409 F.2d 734, 740 (2d Cir. 1969); *United States* v. *716 Cases,* 179 F.2d 174, 176 (10th Cir. 1950); *United States* v. *Two Bags, Poppy Seeds,* 147 F.2d 123, 126-127 (6th Cir. 1945)

The FDA regulation is therefore not merely a construction of a single word in the statute. It amounts to a total restructuring of the law. The rule profoundly subverts the

basic concept of standards of identity. It negates not only the imitation labeling provisions of §343(c), but also the effects of §343(g), its legislative history, and the line of cases construing it, from *Libby, McNeill & Libby* v. *U.S.*, 148 F.2d 71 (2d Cir. 1945) to *National Nutritional Foods Assn.* v. *Weinberger*, 504 F.2d 761, 774-781 (2d Cir. 1974), *cert. denied* 420 U.S. 946 (1975))

Moreover, in cases not directly addressed to imitation labeling, this Court has flatly rejected the same "nutritional equivalence" rationalization which is offered in support of the current FDA regulation. *Carolene Products* v. *United States*, 323 U.S. 18, 23 (1944); *United States* v. *Ninety-Five Barrels of Apple Cider Vinegar*, 265 U.S. 438, 443 (1924). This Court has consistently rejected attempts to introduce subtle exegesis and verbal nicety in the construction of the Food, Drug and Cosmetic Act. *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153, 166 (1958); *United States* v. *Ninety Five Barrels*, 265 U.S. 438, 442 (1924); *United States* v. *Lexington Mill & Elevator Co.*, 232 U.S. 399, 409-10 (1914). See also the use of the term "imitation" in 21 U.S.C. §25.

(2)

Judicial deference is not owing to the FDA's most recent construction of the imitation labeling provisions of 21 U.S.C. §343(c), for several reasons:

(1) FDA's construction of the statute is directly premised upon its understanding of the specific congressional intent underlying §343. The agency has therefore engaged in "the quintessential judicial function of deciding what a statute means." *Bureau of Alcohol Tobacco & Firearms* v *F.L.R.A.*, —— U.S.——, 104 Sup. Ct. 439, 443-445, n.8, 78 L.Ed. 195, 203, n.8 (1983).

(2) FDA's construction of the statute is contrary to this Court's construction in *62 Cases of Jam v. United States,* 340 U.S. 393 (1951) and *Federal Security Administrator* v. *Quaker Oats,* 318 U.S. 218 (1943).

(3) FDA's current construction of the statute is directly contrary to its own long-standing construction of the statute according to the ordinary meaning of the words. *Watt* v. *Alaska,* 451 U.S. 259, 273 (1981); *General Electric Co.* v. *Gilbert,* 429 U.S. 125, 143 (1976).

(4) FDA's original construction was substantially contemporaneous with the 1938 Act, *S.E.C.* v. *Sloan,* 436 U.S. 103 (1978); *Udall* v. *Tallman,* 380 U.S. 1, 16 (1965).

(3)

The Court of Appeals acknowledged that "If we were addressing the validity of the FDA regulation in or about 1973, the year of its promulgation, we might be inclined to reject it." (App., *infra* p. 14a) But, the Court found that Congress' silence during the eleven years since the FDA rule was promulgated "allows us to at least infer that it has acquiesced in the FDA's construction". (App. *infra* 15a) But this Court's decision in *S.E.C.* v. *Sloan,* 436 U.S. 103, 118-119 (1978) clearly teaches that the mere passage of time cannot remedy a fundamental lack of statutory basis. Moreover, the issue has been contested in the courts since *Swift & Co.* v. *Walkley,* 369 F. Sup. 1198 (S.D.N.Y. 1973). It is reasonable to presume that if Congress is aware of the issue at all, it is awaiting the definitive resolution of the legal issue by the Judicial Branch.

(4)

This case presents substantial issues under the rulemaking provisions of the Administrative Procedure Act (5 U.S.C. §552, §553). The line of cases typified by *S.E.C.* v. *Chenery,* 332 U.S. 194 (1947) *("Chenery II")* contemplate the formulation of adjudicative rules of decision, not the adoption of legislative regulations. In *Chenery II,* the Court noted that the agency had "derived its conclusions from the particular facts in the case, its general experience in reorganization matters and its informed view of statutory requirements." *S.E.C.* v. *Chenery Corp.,* 332 U.S. 194, 204 (1947) The Court sanctioned "case-by-case *evolution*" of standards. (332 U.S. at 203) *Castleberry* was an act of creation *ex nihilo.*

In *Castleberry,* the Judicial Officer explicitly found that the product involved was nutritionally inferior and therefore, regardless of the governing standards, must be labeled "imitation". (Finding 6) (40 Agricultural Decisions 1270) His "findings" of an "existing" agency policy (p. 1269-1270), followed by a conditional and hypothetical "adoption" of policy (p. 1278) were both purely gratuitous. The totality of circumstances seem to suggest a conscious agency decision to short-circuit the procedural requirements of the APA.

The distinction between rulemaking and adjudication, usually murky in its application, is sharply illustrated here: The USDA has attempted to "adjudicate" an entire set of detailed prescriptions, complete with definitions, exemptions, exceptions and mathematical standards. USDA itself recognized their legislative character, and began, but

never finished, a rulemaking proceeding. 48 Fed. Reg. 35, 654 (1983) If USDA's action in *Castleberry* is valid, the rulemaking provisions of the APA are meaningless.

Nor can *Castleberry* be regarded as a valid interpretive rule or a statement of general policy, since there was no *Federal Register* publication [5 U.S.C. §552(a)(1)(D)].

(5)

Even if the FDA Imitation Regulation is valid, its language on its face does not demonstrate unavoidable conflict with the New York regulation, and there need not be any such conflict.

II. The Questions Presented Have Nationwide Impact

More than New York's Imitation Cheese Law is at stake in this case. The general food labeling statutes of New York and many other states are directly implicated. More important, the ultimate judgment in this case requires the construction of the three federal statutes which establish a Congressional policy with respect to the labeling of all imitation foods.

The controversy over the validity of FDA's Imitation Regulation deserves this Court's definitive resolution.

The sections of the Food, Drug and Cosmetic Act which are involved [21 U.S.C. §343(c) and (g)] have been construed by this Court on only two occasions: *62 Cases of Jam* v. *United States,* 340 U.S. 593 (1951) and *Federal Security Administrator* v. *Quaker Oats, Co.,* 318 U.S. 218 (1943). This case necessarily entails a reaffirmation or

overruling of those precedents. A plenary exposition of the structure, meaning and purpose of the food standards and labeling provisions of the Food, Drug and Cosmetic Act is needed.

This case also requires the formulation of some outer limits upon an agency's power to adopt legislative rules outside the rulemaking process required by the Administrative Procedures Act. The opinion below prescribes no such limits. Where, as here, the regulation involved directly impacts upon all consumers of meat, as well as upon state regulatory programs, the opportunity for the states and their citizens to participate in the formulation of agency policy should be given more precise safeguards than are afforded by the decision below.

Conclusion

For all of these reasons, the Court should note probable jurisdiction over this appeal.

Respectfully submitted,

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Dated: May 14, 1985

APPENDICES

APPENDIX A

Opinion of the United States Court of Appeals Second Circuit

UNITED STATES COURT OF APPEALS

SECOND CIRCUIT

Nos. 177, 388, Dockets 84-6141, 84-6149

GROCERY MANUFACTURERS OF AMERICA, INC., a Delaware Corporation,

Plaintiff-Appellee Cross-Appellant,

v.

JOSEPH GERACE, Commissioner, New York Department of Agriculture and Markets, and THE NEW YORK DEPARTMENT OF AGRICULTURE AND MARKETS,

Defendants-Appellants Cross-Appellee,

JOHN R. BLOCK, as Secretary of Agriculture of the United States and THE DEPARTMENT OF AGRICULTURE OF THE UNITED STATES, MARGARET M. HECKLER, as Secretary of Health and Human Services of the United States, and THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES,

Additional Defendants on Counterclaim-Appellees.

Argued Sept. 26, 1984

Decided Feb. 14, 1985

Thomas G. Conway, N.Y., Dept. of Agriculture and Markets, Albany, N.Y. (Robert Abrams, Atty. Gen., of the State

of N.Y., New York City, of counsel), for defendant-appellant cross-appellee New York Dept. of Agriculture and Markets.

Franklin H. Stone, Asst. U.S. Atty., S.D. of N.Y., New York City (Rudolph W. Guilliani, U.S. Atty. for the S.D. of N.Y., Jane E. Booth, Asst. U.S. Atty., S.D. of N.Y., Beverly Sherman Nash, U.S. Dept. of Justice, Frederick H. Degnan, Food and Drug Admin., Thomas D. Edmundson, U.S. Dept. of Agriculture, Washington, D.C., of counsel), for defendants on counterclaim-appellees Block and Heckler.

George M. Burditt, Chicago, Ill. (Robert G. Epsteen, Burditt, Bowles & Radzius, Ltd., Chicago, Ill., Sheldon Oliensis, Richard A. DeSevo, Kaye, Scholer, Fierman, Hays & Handler, New York City, of counsel), for plaintiff-appellee cross-appellant Grocery Mfrs. of America.

Before FRIENDLY, MESKILL and PIERCE, Circuit Judges.

MESKILL, Circuit Judge:

This is an appeal from a judgment entered in the United States District Court for the Southern District of New York, Duffy, *J.*, granting the motion of plaintiff-appellee Grocery Manufacturers of America (GMA) for preliminary and permanent injunctive relief. The district court, in a decision reported at 581 F.Supp. 658 (S.D.N.Y.1984), enjoined the enforcement of N.Y.Agric. & Mkts.Law § 63 (section 63), which it found invalid on federal preemption and Commerce Clause grounds.

We affirm in part and reverse in part.

Appendix A

Background

This litigation involves state and federal regulatory schemes that require descriptive labeling of cheese alternatives: products composed wholly or partly of food that looks, smells and tastes like cheese, but is not, in fact, cheese. The major focus of the dispute concerns the use and meaning of the modifier "imitation" as applied to these products. A brief discussion of cheese-making is in order.

Real cheese is made from milk with its milkfat content intact. Cheese alternatives may be made in two ways. One method begins with either milk from which the milkfat has been removed or casein, natural milk protein extracted from milk. The altered milk or casein is then combined with vegetable oil, which substitutes for milkfat. This type of alternative cheese is lower in calories and cholesterol than real cheese. It sells at prices fifty to sixty percent lower than real cheese. The other type of alternative cheese is chemically similar to real cheese but is made wholly or in part with substitute dairy products. This is presumably even less expensive to manufacture than the former. Vitamins and minerals may be added to raise the nutritional level of alternative cheese. Record of Administrative Rulemaking Proceedings in the Adoption of Imitation Cheese Labeling Regulations (before the New York Department of Agriculture and Markets), Record Doc. # 6 at 152-60.

Alleging that New York's imitation cheese law was in conflict with federal labeling requirements and with the Commerce Clause, GMA commenced this litigation with a complaint requesting injunctive and declarative relief

against defendants-appellants New York Department of Agriculture and Markets and the department's Commissioner, Joseph Gerace (collectively New York). New York counterclaimed and included as additional defendants the United States Department of Agriculture (USDA); the United States Department of Health and Human Services (HHS), the bureaucratic parent of the Food and Drug Administration (FDA); and the respective department secretaries. The counterclaim sought to have 21 C.F.R. § 101.3 (1984), the federal regulation that defines the term imitation for purposes of food package labeling, declared invalid.

The text of New York's section 63, enacted in 1982, is set out in the margin.[1] Briefly, it requires that alternative

1. Section 63, N.Y. Agric. & Mkts. Law, provides in its entirety:

1. Whenever the brand name or product designation of imitation cheese or imitation cheese food appears on a package, the brand name or product designation, whichever is larger, shall be immediately preceded, without intervening printed or graphic material by the word imitation and the name of the food imitated, in letters of the same color and on the same contrasting background and of equal size as the brand name or product designation, whichever is larger.

2. On the label of any product containing imitation cheese or imitation cheese food, the product designation shall be immediately preceded or followed by the words "contains imitation cheese" or "contains imitation cheese food" whichever is appropriate, in letters of the same color and on the same contrasting background and of equal size as the product designation.

3. Whenever imitation cheese or imitation cheese food is used in a product which is offered for sale for carry out or on premises consumption, a sign shall be prominently posted at the place of sale which states the product designation of the food followed immediately by the words "contains imitation cheese" or "contains imitation cheese food," whichever is appropriate. The letters on such sign shall be in block letters at least three

(footnote continued on next page)

cheese products feature labels that display promiently the descriptive term "imitation." It also directs that anyone who sells prepared foods containing cheese alternatives, whether for carry out or for consumption on the premises, must display a sign that discloses in three inch letters those foods that contain "imitation cheese." Further, it provides that restaurant menus must append the words "contains imitation cheese" to the item designation of any offering containing alternative cheese. And, finally, alternative cheese products available for use by customers on the premises—as, for example, something resembling grated parmesan—must be conspicuously labeled as "imitation cheese."

Section 63 does not define imitation. The regulations promulgated pursuant to the statute define "imitation cheese" as any food simulating "cheese" as described or standardized by regulation but failing to meet that description or standard. N.Y. Admin.Code tit. 1, § 18.1(c).

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inches in height and on a contrasting background which can be easily read by consumers under normal conditions of purchase.

4. Whenever any product which contains imitation cheese or imitation cheese food product is offered for sale on the menu of any service food establishment, the product designation on such menu shall be immediately followed by the words "contains imitation cheese" or "contains imitation cheese food", whichever is appropriate, in letters of equal size and on a contrasting background.

5. Whenever any imitation cheese or imitation cheese food product is placed on the tables or otherwise made available for use by customers in any service food establishment, the container of such product shall be conspicuously labeled "imitation cheese", or "imitation cheese food product".

6. The commissioner shall promulgate such rules and regulations as are necessary and appropriate to carry out the provisions of this section, including specific identification of imitation cheese and imitation cheese food.

Neither the statute nor any of its regulations is concerned with nutritional values.

The federal scheme implicated here, which establishes the requisite information content of package labels for foods shipped in interstate commerce, involves three federal statutes and two federal agencies. Food labeling generally is governed on the federal level by the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.* (1982), and its regulations, which come under the administrative aegis of the FDA. The FDCA does not contain any express preemption language.

The labeling of meat and poultry products shipped in interstate commerce is specifically controlled by the Federal Meat Inspection Act (FMIA), 21 U.S.C. § 601 *et seq.* (1982), and the Poultry Products Inspection Act (PPIA), 21 U.S.C. § 451 *et seq.* (1982), and their respective regulations, 9 C.F.R. § 317 *et seq.* (1984). The FMIA and the PPIA are administered by the USDA. Both statutes contain substantially identical preemption language which permits some concurrent state enforcement but prohibits state "[m]arking, labeling, packaging, or ingredient requirements in addition to, or different than, those" mandated by federal law. 21 U.S.C. § 678 (FMIA); *see also* 21 U.S.C. § 467e (PPIA).

The FDCA specifically prohibits, among other things, misbranded foods. Under the FDCA, a food is misbranded if it is sold under the name of any other food, 21 U.S.C. § 343(b), or if it purports to be a food, such as cheese, for which a standard of identity has been prescribed by regulation and it does not conform exactly to that standard, 21 U.S.C. § 343(g). In addition, a food that "is an imitation

of another food" is misbranded unless its label contains the word "imitation" in prominent letters immediately preceding the name of the food imitated. 21 U.S.C. § 343(c).

The FDCA does not define imitation; that task was accomplished by regulation in 1973. An imitation food is defined as a food which "is a substitute for and resembles another food but is nutritionally inferior to that food." 21 C.F.R. § 101.3(e)(1). Nutritional inferiority is determined by comparing the percentages of so-called "essential nutrients" in the substitute to those in the food for which it substitutes. 21 C.F.R. § 101.3(e)(4). The essential nutrients are protein and the nineteen vitamins and minerals for which the federal government has established recommended daily allowances (U.S. RDAs). *Id.;* § 101.-9 (c)(7)(iv). Basically, if the substitute contains less of any essential nutrient present to a measurable degree in the food substituted for, the substitute must be labeled with the word "imitation."

A nutritionally equivalent or superior substitute food would be misbranded under federal law if it was labeled with the term "imitation."[2] Such foods must be identi-

2. This outcome could be modified by the exercise of 21 C.F.R. § 101.3(e)(4)(iii):

> If the Commissioner concludes that a food is a substitute for and resembles another food but is inferior to the food imitated for reasons other than those set forth in this paragraph, he may propose appropriate revisions to this regulation or he may propose a separate regulation governing the particular food.

fied by an appropirate common or usual name or, if none exists, a descriptive term.[3] The fact that such foods are substitute foods would thus be evident from the foods' labels, albeit less so than if the word "imitation" was used.

The FMIA and the PPIA contain misbranding provisions essentially identical to the FDCA's. *Compare* 21 U.S.C. § 453(h) (PPIA) *and* § 601(n) (FMIA) *with* 21 U.S.C. § 343 (FDCA). Unlike the FDCA, both the PPIA and the FMIA, to prevent misbranding, require that all proposed labels be reviewed and approved by USDA agents prior to use. 21 U.S.C. § 457(c) & (d) (PPIA); § 607(d) & (e) (FMIA). Neither the text of nor the regulations under either the FMIA or the PPIA define imitation. However, the USDA avers that it has adopted the FDA's definition.

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3. Subsection (2) of 21 C.F.R. § 101.3(e) provides:

> A food that is a substitute for and resembles another food shall not be deemed to be an imitation provided it meets each of the following requirements:
>
> (i) It is not nutritionally inferior to the food for which it substitutes and which it resembles.
>
> (ii) Its label bears a common or usual name that complies with the provisions of § 102.5 of this chapter and that is not false or misleading, or in the absence of an existing common or usual name, an appropriately descriptive term that is not false or misleading. The label may, in addition, bear a fanciful name which is not false or misleading.

Subsection (3) further restricts the ambit of "imitation:"

> A food for which a common or usual name is established by regulation (e.g., in a standard of identity pursuant to section 401 of the act, in a common or usual name regulation pursuant to Part 102 of this chapter, or in a regulation establishing a nutritional quality guideline pursuant to Part 104 of this chapter), and which complies with all of the applicable requirements of such regulation(s), shall not be deemed to be an imitation.

Thus federal labeling requirements for alternative cheese products and for meat and poultry products containing cheese alternatives are uniform. If the product is nutritionally inferior to the food it resembles, it must be labeled "imitation." If, however, it is nutritionally equivalent or superior to its model, it would be misbranded if it was labeled "imitation."

In the court below, the parties agreed and the district judge found—that there were no unresolved material issues of fact. 581 F.Supp. at 661. The judge therefore deemed summary judgment as to GMA's motion for preliminary and permanent injunctive relief appropriate. *Id.* Accordingly, the court held that New York's labeling requirements as applied to alternative cheese were preempted by the FDCA because the federal requirements, as applied in compliance with the FDA's definition of imitation, and the state requirements were in actual conflict. Further, it held that the state labeling requirements as applied to meat and poultry products containing alternative cheese were preempted by the FMIA and the PPIA because the USDA's adoption of the FDA's definition of imitation created actual conflict between the state and federal schemes and, also, because of the express preemption language in the federal statutes. Finally, the district court held that the sign, menu and container provisions were invalid because they placed an undue burden on interstate commerce in violation of the Commerce Clause.

On appeal, New York challenges all three of the district court's conclusions. It argues that the state labeling provisions are not preempted by the FDCA because the

federal regulation defining imitation violates the meaning and purpose of the FDCA and is therefore invalid. Invalidation of the regulation, of course, would vitiate the actual conflict between the state and federal schemes. New York also maintains that even if the definition is valid under the FDCA, the USDA's adoption of the definition was procedurally defective. Thus, New York reasons, the state statute is not in conflict with either the FMIA or the PPIA. Further, New York claims that the requirements of the state statute fall outside the reach of the preemption provisions of the FMIA and the PPIA. And finally, New York contends that the sign, menu and container provisions do not violate the Commerce Clause.

Discussion

I. *Federal Preemption*

A. *Generally*

The preemption doctrine is rooted in the Supremacy Clause of the United States Constitution, Art. VI, cl. 2. Its application compels judicial divination of congressional intent. Preemption is mandated in two general contexts: when a state legislates in a field that Congress intended to occupy totally and when the state and federal laws actually conflict.

Any state law intruding upon an area that Congress intended to control exclusively is preempted, "whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525, 97

S.Ct. 1305, 1309, 51 L.Ed.2d 604 (1977). Absent explicit preemption language, congressional intent to occupy the field regulated may nevertheless be inferred on the basis of the pervasiveness of the federal scheme, the dominance of the federal interest involved or because of the federal statute in combination with the nature of its directives reveals the purpose to preclude state action. *Fidelity Federal Savings & Loan Association v. de la Cuesta,* 458 U.S. 141, 153, 102 S.Ct. 3014, 3022, 73 L.Ed.2d 664 (1982); *Rice v. Santa Fe Elevator Corp.,* 331 U.S. 218, 230, 67 S.Ct. 1146, 1152, 91 L.Ed. 1447 (1947).

"Even where Congress has not entirely displaced state regulation in a specific area, state law is pre-empted to the extent that it actually conflicts with federal law." *Pacific Gas & Electric Co. v. State Energy Resources Conservation & Development Commission,* 461 U.S. 190, 204, 103 S.Ct. 1713, 1722, 75 L.Ed.2d 752 (1983). All actual conflict exists "when it is impossible to comply with both state and federal law, *Florida Lime & Avocado Growers, Inc. v. Paul,* 373 U.S. 132, 142-143 [83 S.Ct. 1210, 1217, 10 L.Ed.2d 248] (1963), or where the state law stands as an obstacle to the accomplishment of the full purposes and objectives of Congress, *Hines v. Davidowitz,* 312 U.S. 52, 67 [61 S.Ct. 399, 404, 85 L.Ed. 581] (1941)." *Silkwood v. Kerr-McGee Corp.,* —— U.S. ——, ——, 104 S.Ct. 615, 621, 78 L.Ed.2d 443 (1984).

Moreover, preemption is compelled not only when the conflict involves a federal statute, but also when it involves valid federal regulations. Provided that they are reasonable exercises of an agency's duly authorized discretion and not in conflict with congressional intent, *United*

States v. Shimer, 367 U.S. 374, 381-82, 81 S.Ct. 1554, 1559-60, 6 L.Ed.2d 908 (1961), "[f]ederal regulations have no less preemptive effect than federal statutes." *Fidelity Federal Savings & Loan*, 458 U.S. at 153, 102 S.Ct. at 3022; *accord Blum v. Bacon*, 457 U.S. 132, 145-46, 102 S.Ct. 2355, 2363-64, 72 L.Ed.2d 728 (1982).

B. *The FDCA*

The preemptive effect of the FDCA depends entirely on whether the FDA's definition of imitation is valid and therefore entitled to our deference. Characterizing 21 C.F.R. § 101.3(e) as an attempt to administratively amend the FDCA, New York argues that we should disregard the regulation and give the word imitation its ordinary meaning.

New York's challenge to the FDA regulation is grounded in the language, legislative history and, most particularly, the pre-1973 (i.e., prior to the promulgation of 21 C.F.R. § 101.3(e)) judicial construction of the FDCA and its predecessor statutes. The fulcrum of the state's argument is the United States Supreme Court decision in *62 Cases of Jam v. United States*, 340 U.S. 593, 71 S.Ct. 515, 95 L.Ed. 566 (1951). That litigation involved a product labeled "Delicious Brand Imitation Jam" which the government claimed was misbranded because it resembled fruit jam but contained less than the federally standardized amount of fruit. The controversy actually involved a perceived conflict between the FDCA subsection deeming a food misbranded if it substituted for and resembled another food but was not labeled "imitation" and the subsection deeming a food misbranded if it purported to be

a food that had been standardized by regulation. In concluding that the product purported to be not fruit jam but imitation jam and, therefore, that it was not misbranded, the Court reasoned that "the ordinary meaning of the statute" should control. 340 U.S. at 600, 71 S.Ct. at 520.

The *62 Cases of Jam* Court discussed and distinguished an earlier Supreme Court case relied on by New York and also decided under the FDCA, *Federal Security Administrator v. Quaker Oats Co.*, 318 U.S. 218, 63 S.Ct. 589, 87 L.Ed. 724 (1943). *62 Cases of Jam*, 340 U.S. at 598-99, 71 S.Ct. at 519. In upholding the government's contention that a food was misbranded even though its label disclosed the presence of a nondeleterious substance that was not a standard ingredient, the *Quaker Oats* Court explained that the purposes of the FDCA went beyond mere prohibition of false and misleading labeling. Such prohibition alone could not

> protect the consumer from "economic adulteration," by which less expensive ingredients were substituted, or the proportion of more expensive ingredients diminished, so as to make the product, although not in itself deleterious, inferior to that which the consumer expected to receive when purchasing a product with the name under which it was sold.

318 U.S. at 230, 63 S.Ct. at 596. To guard the integrity of food products, the act authorized promulgation of standards of identity, requiring "informative labeling only where no such standard has been promulgated, where the food did not purport to comply with a standard, or where the regulations permitted optional ingredients and required their mention on the label." *Id.*

New York also refers us to *United States v. 651 Cases, More or Less, of Chocolate Chil-Zert,* 114 F.Supp. 430 (N.D.N.Y. 1953) (*Chil-Zert*), which, drawing on the Supreme Court precedents, attempted to flesh out the judicial definition of imitation. "The word connotes inferiority in the sense that [the product] is cheapened by the substitution of ingredients[;]" the result is "something less than the genuine article." *Id.* at 432 (citations omitted).

New York correctly notes that the FDA's regulatory definition of imitation is at odds with the judicial gloss placed on the term. Consequently, the state avers, we should disregard the definition and follow the reasoning of *Swift & Co. v. Walkley,* 369 F.Supp. 1198 (S.D.N.Y. 1973), decided under the FMIA. The *Swift* Court acknowledged that the USDA, in approving a label for a frankfurter-like product that did not contain the word "imitation," had relied on the findings of the *White House Conference on Food, Nutrition and Health Final Report* 120 (1969), J.App. at 139 (*White House Report*), particularly that "[c]onsumers are reluctant to purchase products labelled 'imitation' even though the products are very good and highly nutritious." 369 F.Supp. at 1200 (quoting USDA official's affidavit). Nevertheless, the court rejected the USDA's position and upheld the state's ban on the sale of the product because, lacking the modifying "imitation frankfurters," the product was misbranded.

If we were addressing the validity of the FDA regulation in or about 1973, the year of its promulgation, we might be inclined to reject it. But the regulation has been in effect for eleven years. Congress' failure during this period to alter the relevant statutory language or to other-

wise condemn the regulatory definition, while not a fail-safe guide, allows us at least to infer that it has acquiesced in the FDA's construction. *See, e.g., Haig v. Agee,* 453 U.S. 280, 300, 101 S.Ct. 2766, 2778, 69 L.Ed.2d 640 (1981); *United States v. Rutherford,* 442 U.S. 544, 554 & n. 10, 99 S.Ct. 2470, 2470 & n. 10, 61 L.Ed.2d 68 (1979); *Zemel v. Rusk,* 381 U.S. 1, 11, 85 S.Ct. 1271, 1278, 14 L.Ed.2d 179 (1965); *Norwegian Nitrogen Products Co. v. United States,* 288 U.S. 294, 313, 53 S.Ct. 350, 357, 77 L.Ed. 796 (1933); *Costanzo v. Tillinghast,* 287 U.S. 341, 345, 53 S.Ct. 152, 153, 77 L.Ed. 350 (1932); *but see SEC v. Sloan,* 436 U.S. 103, 119-21, 98 S.Ct. 1702, 1712-13, 56 L.Ed.2d 148 (1978). Moreover, the two courts of appeals that have considered the regulation have upheld its validity. *National Milk Producers Federation v. Harris,* 653 F.2d 339 (8th Cir.1981); *Federation of Homemakers v. Schmidt,* 539 F.2d 740 (D.C. Cir. 1976).

We could scarcely improve on the D.C. Circuit's perspicacious decision in *Federation of Homemakers* sustaining the FDA's definition against a challenge brought by a national consumer group. Addressing arguments similar to those raised by New York, the court explained that the earlier and undeniably reasonable judicial construction of imitation did not "prevent the promulgation of an equally reasonable definition by the agency charged with administering the [FDCA]." 539 F.2d at 743. We concur with that court; "our deference to the enforcing agency's interpretation limits our review to determining only whether the regulation violates the language of the statute or is arbitrary and capricious." *Id.* The FDA's regulation furthers the twin goals of "better informing con-

sumers so that they may exercise a knowledgeable choice of differing foods within general categories" and "encouraging manufacture of nutritional food products;" it is both reasonable and within the ambit of the agency's discretion. *Id.* at 744; *accord White House Report* at 120, J.App. at 139.

Unless contrary to the indications of the statute itself, *see SEC v. Sloan*, 436 U.S. at 117-19, 98 S.Ct. at 1711-12, the construction and application of a statute by the agency charged with its administration is entitled to substantial deference. *Blum v. Bacon*, 457 U.S. at 141, 102 S.Ct. at 2361; *United States v. Rutherford*, 442 U.S. at 553, 99 S.Ct. at 2475; *Udall v. Tallman*, 380 U.S. 1, 16, 85 S.Ct. 792, 801, 13 L.Ed.2d 616 (1965). The FDA's definition of imitation is entitled to our deference.

Thus, as applied to alternative cheese, the New York labeling scheme is in direct conflict with its federal counterpart. Including the term imitation on the label of a nutritionally superior alternative cheese in order to comply with New York law, would render the product misbranded under federal law. Compliance with both the state and federal requirements is impossible. To the extent that it attempts to regulate the labeling of alternative cheese, the New York law is preempted.

C. *The FMIA and the PPIA*

Whether the New York law as applied to meat and poultry products that contain alternative cheese is also preempted requires us to determine whether the reach of the preemption provisions of the FMIA and the PPIA

extends to the New York labeling requirements. This inquiry requires us to decide, also, whether the USDA's adoption of the FDA's regulatory definition of imitation was valid.

New York argues that the adoption was improper because it was not in accordance with the rulemaking provisions of the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* (1982). The district court determined, and the federal parties agree, "that the USDA's imitation food policy is more akin to a statement of general policy or an interpretive rule than to a rule which requires formal notice and comment proceedings." 581 F.Supp. at 665. The federal agencies also claim that the USDA's action could be correctly characterized as an express adoption of a standing policy through adjudication.

It is well established that an agency may adopt prospective rules of general effect through either rulemaking or adjudication; the choice of method rests within the discretion of the agency. *E.g., NAACP v. FPC,* 425 U.S. 662, 668, 96 S.Ct. 1806, 1810, 48 L.Ed.2d 284 (1976); *NLRB v. Bell Aerospace Co.,* 416 U.S. 267, 290-95, 94 S.Ct. 1757, 1769-72, 40 L.Ed.2d 134 (1974); *SEC v. Chenery Corp.,* 332 U.S. 194, 202-03, 67 S.Ct. 1575, 1580, 91 L.Ed. 1995 (1947); *New York State Commission on Cable Television v. FCC,* 669 F.2d 58, 62 n. 9 (2d Cir.1982). In support of its claim of adoption through adjudication, the USDA cites *In re Castleberry's Food Co.,* 40 Agric. Dec. 1262 (1981), a USDA adjudicative proceeding under the FMIA, which expressly adopted what it identified as agency practice: use of the FDA definition of imitation in the case-by-case approval of food labels. *Id.* at 1277-78. Indeed, as the

court in *Swift & Co. v. Walkley,* 369 F.Supp. at 1200, indicated, the agency had begun narrowing the application of the term "imitation" as early as 1970, just after the issuance of the *White House Report.* Moreover, formal notice and comment rulemaking procedures concerning the practice were initiated on or about August 5, 1983. 48 Fed. Reg. 35,654 (1983). The initiating notice explained that

> [t]he proposed disclosure requirement for substitute and imitation cheese ingredients would not affect current requirements for "imitation" labeling. Thus, for example, in addition to the disclosure statement concerning its cheese content, any standardized meat product whose required ingredients include "cheese" would still be required to bear "imitation" labeling, if the use of imitation cheese caused the product to be nutritionally inferior to the standardized product.

Id. at 35,658.

Even if it should be classified as an interpretive rule or a statement of general policy, rather than as a formal rule adopted via adjudication, the USDA's practice of following the FDA definition of imitation when reviewing meat and poultry product labels is valid. The distinctions between formal rules and interpretive rules or general statements of policy are often vague. *Noel v. Chapman,* 508 F.2d 1023, 1029-30 (2d Cir.), *cert. denied,* 423 U.S. 824, 96 S.Ct. 37, 46 L.Ed.2d 40 (1975); *Pacific Gas & Electric Co. v. FPC,* 506 F.2d 33, 37-40 (D.C.Cir.1974). But we need not explore the nuances. If the USDA's practice is merely interpretive, it is a reasonable interpretation and therefore entitled to judicial respect. *Ford Motor Credit Co. v. Milhollin,* 444 U.S. 555, 566, 100 S.Ct. 790, 797, 63

L.Ed.2d 22 (1980); *National Nutritional Foods Association v. Weinberger,* 512 F.2d 688, 696 (2d Cir.), *cert. denied,* 423 U.S. 827, 96 S.Ct. 44, 46 L.Ed.2d 44 (1975). And, while we recognize that we are not bound by interpretive rules, *American Postal Workers Union v. United States Postal Service,* 707 F.2d 548, 560 (D.C.Cir.1983), *cert. denied,* —— U.S. ——, 104 S.Ct. 1594, 80 L.Ed.2d 126 (1984); *Board of Education v. Harris,* 622 F.2d 599, 612-13 (2d Cir.1979), *cert. denied,* 449 U.S. 1124, 101 S.Ct. 940, 67 L.Ed.2d 110 (1981), we discern no reason to reject the USDA's longstanding interpretation of the FMIA and PPIA misbranding provisions. *Cf. United States v. Clark,* 454 U.S. 555, 565, 102 S.Ct. 805, 811, 70 L.Ed.2d 768 (1982) ("Although not determinative, the construction of a statute by those charged with its administration is entitled to great deference, particularly when that interpretation has been followed consistently over a long period of time.") Consequently, the New York requirements are "different from" the federal requirements, as administered, and they are therefore preempted.

Notwithstanding the conflict created by its use of "imitation," the New York law imposes other labeling requirements that are "in addition to[] or different than" the federal requirements. The preemption language of the FMIA, essentially identical to that in the PPIA, was addressed by the Supreme Court in *Jones v. Rath Packing Co.,* 430 U.S. at 528-32, 97 S.Ct. at 1311-13. The Court had before it the federal and California standards of accuracy for net weight labeling. California's inspection sampling technique implicitly permitted the inevitable slight deviations resulting from the manufacturing process.

But it did not allow for weight loss "resulting from moisture loss during the course of good distribution practice." *Id.* at 531, 97 S.Ct. at 1312. In contrast, the USDA had interpreted the FMIA to permit reasonable variations, including such moisture loss. *Id.* at 529, 97 S.Ct. at 1311. Thus, the Court held that the California regulations were explicitly preempted by the FMIA. *Id.* at 532, 97 S.Ct. at 1313.

Analogously, New York's section 63 mandates the precise size of the letters in and relative location of the word "imitation" on package labels. These requirements do not comport exactly with the federal specifications.[4] Therefore, the state requirements are preempted.

II. *Commerce Clause*

Our preemption holdings make it unnecessary for us to determine whether the New York labeling provisions are invalid under the Commerce Clause as well. Accordingly, we direct our Commerce Clause analysis only to the New York sign, menu and container provisions, subsections 3, 4 and 5 of section 63.[5]

The Supreme Court has mapped our course quite clearly:

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4. *See* section 63(1), *supra* note 1. Te PPIA misbranding section, 21 U.S.C. § 453(h)(3), and the FMIA misbranding provision, 21 U.S.C. § 601(n)(3), both provide that a product is misbranded

> if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and immediately thereafter, the name of the food imitated.

5. Similarly, we do not address GMA's claim that the labeling provisions violate the Equal Protection Clause.

> Where [a state] statute regulates even-handedly to effectuate a legitimate local public interest, and its effects on interstate commerce are only incidental, it will be upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits. *Huron Cement Co. v. Detroit*, 362 U.S. 440, 443 [80 S.Ct. 813, 815, 4 L.Ed.2d 852]. If a legitimate local purpose is found, then the question becomes one of degree. And the extent of the burden that will be tolerated will of course depend on the nature of the local interest involved, and on whether it could be promoted as well with a lesser impact on interstate activities.

Pike v. Bruce Church, Inc., 397 U.S. 137, 142, 90 S.Ct. 844, 847, 25 L.Ed.2d 174 (1970).

The district court correctly determined that the New York law regulates even-handedly. 581 F.Supp. at 670. The state requirements do not distinguish between alternative cheese products from in-state manufacturers and those from out-of-state manufacturers. And, to the extent that they indirectly advantage the dairy industry, that effect is not necessarily limited to in-state dairy producers.[6]

Further, the local interest which the New York scheme was designed to protect is a legitimate one. States have traditionally acted to protect consumers by regulating foods produced and/or marketed within their borders. *E.g., Florida Lime & Avocado Growers v. Paul*, 373 U.S. 132, 144, 83 S.Ct. 1210, 1218, 10 L.Ed.2d 248 (1963). Under federal law, foods packaged for wholesale or retail market-

6. Some cheese alternatives contain a percentage of real cheese; many are made with diary products. Thus, any disadvantage to the alternative cheese product manufacturers may have a similar impact on at least some segment of the New York diary industry.

ing are labeled to indicate that they fit into one of three categories: real cheese, alternative cheese that meets or exceeds federal nutritional guidelines or alternative cheese that falls below nutritional guidelines. New York has determined that patrons of food service establishments and restaurants—heretofore wholly uninformed as to the composition of any cheese-like substance served to them—are entitled to know at least whether they are buying real cheese or a cheese alternative. The record shows that health and nutrition professionals strongly disagree about the intrinsic value of the federal nutritional guidelines applied to alternative cheese products. *See, e.g.,* In re Considering the Adoption of Regulations Relating to Labeling and Notification Required Prior to the Serving of Imitation Cheese, Imitation Cheese Food and Products Containing Imitation Cheese or Imitation Cheese Food, J.App. at 45, 50 (rejecting federal government's nutritional equivalency arguments); Record of Administrative Rulemaking Proceedings in the Adoption of Imitation Cheese Labeling Regulations, vol. 2 at 557-59, Record Doc. #7 at 557-59 (reproducing Kotula & Briggs, "The Nutritional Aspects of Imitation and Substitute Foods," 46 Nutrition News, no. 1 at 1-3 (Feb.1983), which rejects the premise of the federal government's nutritional equivalency arguments). The very existence of this controversy persuades us that New York's nutritional concerns are not unreasonable. In addition to promoting those concerns, the state requirements are intended to prevent deception and unfair competition, to promote honestly and fair dealing and to permit consumers to clearly discern whether they are buying real

cheese or not. We believe that the sign, menu and container provisions effectuate a legitimate, local public purpose.

The final step of our Commerce Clause analysis requires us to balance the local interest served against the burden imposed on interstate commerce by the disputed sections. Interestingly, the federal government did not join in GMA's challenge to the sign, menu and container provisions. Neither did the operators of any restaurants or food service establishments, though they are surely the persons most directly affected by these provisions.

The only evidence in the record establishing a connection between the provisions and interstate commerce comprises three affidavits.[7] The affidavits, at bottom, claim but a single impact on commerce: restaurants and food service establishments will discontinue the use of alternative cheese products rather than comply with the sign, menu and container provisions. Of those filed, only the affidavit of Olindo DiFrancesco, President of Olindo's Food, Inc., really supports the alleged purchasing shift, J.App. at 401; the others are merely conclusory, *see* affidavit of George W. Cawman, J.App. at 201; affidavit of Thomas Brennan, J.App. at 417. Olindo's Food, Inc. distributes foods, including cheese and cheese alternatives to restaurants, pizza parlors and grocery stores. According to DiFrancesco, prior to passage of the New York law, most of the pizzerias that purchased from Olindo's Food used a mozzarella substitute. After

7. The district court erroneously determined that interstate commerce would somehow be burdened because restauranteurs and other food service operators would be unable to determine whether items that they used in food preparation would require sign, menu or container disclosure. But because those items would presumably be labeled in accordance with federal requirements, the label would show that the item was not real cheese.

the law's passage, however, sales of the cheese alternative began to decline. Naming two specific customers (representing thirty-seven pizza parlors) who discontinued such purchases, DiFrancesco averred that his sales of cheese alternatives have dropped from 12,000 to 2,000 pounds per week or approximately $7,500 per week. His losses have not been offset by increases in sales of real mozzarella. Ironically, Olindo's Food is located in New York State.

The facts are not disputed in this case. Thus, we accept that sales of cheese alternatives to food service establishments have declined. But this decline is susceptible of at least two interpretations. One is that the sign, menu and container requirements are so onerous that food service establishments and restaurants are willing to use real cheese and thus forego the advantages of cheese substitutes, economic and otherwise, rather than comply. Equally probable, however, is that food service establishment operators and restauranteurs will not use less expensive cheese alternatives in place of real cheese of they have to disclose that use to customers.

GMA relies substantially on *American Meat Institute v. Ball,* 550 F.Supp. 285 (W.D.Mich.1982), *aff'd on other grounds sub nom. American Meat Institute v. Pridgeon,* 724 F.2d 45 (6th Cir.1984), for its Commerce Clause argument. That decision struck down a Michigan law that required federally inspected meats not in compliance with Michigan ingredient requirements to be accompanied by a prominent placard stating, in part, "The following products do not meet Michigan's high meat ingredient standards but do meet lower federal standards." *Id.* at 286 n. 1. However, in that case the court found that the federal

standards, in many respects, were actually higher than Michigan's and that the required placard was thus not only misleading but wrong. Accordingly, it held that the state law did not promote a legitimate state interest and, therefore, that it violated the Commerce Clause.

The New York sign, menu and container provisions do not produce such an inaccurate or misleading result that they fail to serve a legitimate state purpose. And although complying with the sign posting requirement will certainly not enhance the decor of most restaurants, that negative is not a violation of the Commerce Clause. Indeed, consumers seeking low cholesterol foods may be benefited by the prominence of the signs. The disputed provisions here are the result of legislative choices. The arguments against the provisions "relate[] to the wisdom of the statute, not to its burden on commerce." *Exxon Corp. v. Governor of Maryland,* 437 U.S. 117, 128, 98 S.Ct. 2207, 2215, 57 L.Ed.2d 91 (1978). That wisdom is better reconsidered in Albany than Foley Square.

A state regulatory scheme "is not invalid simply because it causes some business to shift from a predominantly out-of-state industry to a predominantly in-state industry. Only if the burden on interstate commerce *clearly outweighs* the State's legitimate purposes does such a regulation violate the Commerce Clause." *Minnesota v. Clover Leaf Creamery Co.,* 449 U.S. 456, 474, 101 S.Ct. 715, 729, 66 L.Ed. 2d 659 (1981) (emphasis added). The disputed provisions place a relatively minor burden on commerce and advance an important state interest. We are not persuaded that the use of a term other than "imitation" or the posting of smaller signs would both serve the local interest and have

a lesser effect on commerce. We therefore reverse the district court and hold that the sign, menu and container provisions, subsections 3, 4 and 5 of section 63, do not violate the Commerce Clause.

We draw additional support for our conclusion from the language of 21 U.S.C. § 25 (1982). That section provides, in part, that "imitation cheese[] or any substance in the semblance of . . . cheese not the usual product of the dairy and not made exclusively of pure and unadulterated milk or cream transported into any State . . . and remaining therein for use, consumption, sale or storage" is subject to the laws of that state. Enacted to override judicial decisions that prevented states from prohibiting sales of oleomargarine, the statute "indicates a Congressional purpose not to hinder the free exercise of state power, except as it may be inconsistent with the federal legislation." *Cloverleaf Butter Co. v. Patterson,* 315 U.S. 148, 161, 62 S.Ct. 491, 499, 86 L.Ed. 754 (1942). The sign, menu and container provisions are not inconsistent with federal legislation governing cheese alternatives because they address an area in which Congress has not acted. The expansiveness of 21 U.S.C. § 25 thus confers upon those provisions, if not a shield, at least a sturdy buffer against the Commerce Clause.

III. *Equal Protection*

GMA also alleged in its complaint that the sign, menu and container provisions violated the Equal Protection Clauses of the federal, U.S. Const.amend. XIV, § 1, and state, N.Y. Const.art. 1, § 11, constitutions. Because the district court held that the provisions were void under the

Commerce Clause, it did not reach the equal protection issue. We find GMA's claim wholly unpersuasive.

As applied to this type of legislation, the federal and state guarantees of equal protection prohibit statutory classifications that embody distinctions not rationally related to the object of the legislation. *Barry v. Barchi,* 443 U.S. 55, 67, 99 S.Ct. 2642, 2650, 61 L.Ed.2d 365 (1979); *New York v. Acme Markets,* 37 N.Y.2d 326, 331-32, 372 N.Y.S.2d 590, 595, 334 N.E.2d 555, 558 (1975). We have already discussed the legitimate interest advanced by the sign, menu and container provisions. We have stated our belief that those requirements, which distinguish between producers of real cheese and manufacturers of cheese alternatives, reasonably address New York's legitimate concerns. Accordingly, we conclude that the provisions establish classifications rationally related to the state's purpose and thus do not violate equal protection.

IV. *Attorney's Fees*

GMA also argues that, as a prevailing party on a 42 U.S.C. § 1983 (1982) claim, it is entitled to reasonable attorney's fees as authorized by 42 U.S.C. § 1988 (1982). We need not determine whether this litigation is even remotely related to the type in which Congress intended that attorney's fees be awarded. Our decision is mandated by the language of 42 U.S.C. § 1988, which leaves the decision whether to award fees solely to the discretion of the trial judge. Judge Duffy specifically denied GMA's request. 581 F.Supp. at 672. We see no abuse of discretion here.

Appendix A

CONCLUSION

To the extent that it held the labeling provisions of the New York statute, N.Y. Agric. & Mkts. Law § 631(1) & (2), and their accompanying regulations in violation of the Supremacy Clause, the decision of the district court is affirmed. Insofar as it held that the sign, menu and container provisions, N.Y.Agric. & Mkts. Law § 63(3), (4) & (5), and their accompanying regulations in violation of the Commerce Clause, it is reversed. We affirm the denial of attorney's fees.

APPENDIX B

Opinion and Order of United States District Court for the Southern District

UNITED STATES DISTRICT COURT

S.D. NEW YORK

No. 83 Civ. 8629 (HFW)

GROCERY MANUFACTURERS OF AMERICA, INC., a Delaware Corporation,

Plaintiff,

v.

JOSEPH GERACE, Commissioner, New York Department of Agriculture and Markets, and the New York Department of Agriculture and Markets,

Defendants,

JOHN R. BLOCK, Secretary of Agriculture of the United States and the Department of Agriculture of the United States, Margaret M. Heckler, Secretary of Health and Human Services of the United States and the Department of Health and Human Services of the United States,

Additional Defendants on Counterclaim.

March 8, 1984.

MEMORANDUM DECISION

KEVIN THOMAS DUFFY, District Judge.

Plaintiff Grocery Manufacturers of America ("GMA") has filed a complaint seeking injunctive and declaratory relief against the New York State Department of Agri-

culture and Markets ("Department") and Joseph Gerace, Commissioner the ("Commissioner") of the Department.[1] GMA claims, *inter alia*, that existing federal statutes and regulations governing the labeling of imitation foods including the labeling of imitation cheese products preempts a recently enacted New York statute, N.Y.Agric. & Mkts. Law § 63 (McKinney Supp.1983), and its implementing regulations, 1 NYCRR Part 18. The federal regulations require only that nutritionally inferior products be labeled imitation. The New York statute, on the other hand, requires that all products that resemble or are intended to substitute for traditional or standardized cheese products —whether nutritionally inferior, superior, or equivalent— be labeled imitation.

GMA claims that this alleged intrusion into a federally regulated field violates the Due Process, Commerce, Equal Protection and Supremacy Clauses of the United States Constitution and the Due Process and Equal Protection Clauses of the New York Constitution. Plaintiff also seeks relief under 42 U.S.C. § 1983 and requests attorneys fees. The matter is presently before me on plaintiff's motion for a preliminary injunction. The parties agree and I find that there are no unresolved material issues of fact. Summary judgment as to plaintiff's motion for a preliminary and permanent injunction is therefore appropriate. *See* Fed.R.Civ.P. 56. To evaluate plaintiff's arguments, I turn first to an in depth description of the relevant statutes and regulations.

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1. The United States Department of Agriculture and the United States Food and Drug Administration have responded as additional defendants on the Commissioner's counterclaim.

Appendix B

BACKGROUND

The labeling of all food products shipped in interstate commerce is regulated generally by the Federal Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, and its implementing regulations promulgated by the FDA. 21 C.F.R. § Part 100, *et seq.* The Act requires that the label of a food bear its "common or usual name . . . if any there be," 21 U.S.C. § 343(i), and prohibits the sale of a food under the name of another food. 21 U.S.C. § 343(b). The FDCA further provides that a food which is an imitation of another food product is misbranded "unless the label bears, in type of uniform size and prominence, the word 'imitation' and, immediately thereafter, the name of the food imitated." 21 U.S.C. § 343(c). The statute, however, does not define the word "imitation." In 1973, the Food and Drug Administration ("FDA") promulgated regulations defining imitation food as food which "is a substitute for and resembles another food but is nutritionally inferior to that food." 21 C.F.R. § 101.3(e).[2] The regulations also provide that a substitute food that is not nutritionally inferior must be identified by an appropriate common or usual name or, if none exists, a descriptive term. *See* 21 C.F.R. §§ 102.1(a) & (b); 21 C.F.R. § 1.17. Violators of the FDCA are subject to both civil and criminal sanctions. 21

2. Nutritionally inferior is defined in 21 C.F.R. § 101.3(e)(4) as:

(i) Any reduction in the content of an essential nutrient that is present in a measurable amount, but does not include a reduction in the caloric or fat content . . . (ii) For the purpose of this section, a measurable amount of an essential nutrient in a food shall be considered to be 2 percent or more of the U.S. RDA of protein of any vitamin or mineral listed under § 105.3(b) of this chapter per average usual serving, or where the food is customarily not consumed directly, per average usual portion, as established in § 101.9.

U.S.C. §§ 332-34. Unlike its counterparts in meat, poultry and packaging, the FDCA contains no express preemption provision.[3]

The production and labeling of all meat and poultry food products shipped in interstate commerce is regulated by the Federal Meat Inspection Act ("FMIA"), 21 U.S.C. § 601, *et seq.*, the Federal Poultry Products Inspection Act ("PPIA"), 21 U.S.C. § 451 *et seq.*, and their respective implementing regulations, 9 C.F.R. § 317, *et seq.* Both the FMIA and the PPIA are administered by the United States Department of Agriculture ("USDA") which has the authority to approve all labels for meat and poultry food products prior to their shipment in interstate commerce. 21 U.S.C. §§ 607(d)(meat) & 457(d)(poultry). The misbranding provisions of the FMIA and the PPIA are substantially identical to the FDCA provisions. *Compare* 21 U.S.C. § 343(c) *with* 21 U.S.C. §§ 453(h)(poultry) & 601(n)(meat). No formal regulation has been issued defining "imitation" under either the FMIA or the PPIA, however, proposed rules are presently pending, 44 Fed. Reg. 75991, 76007-09 (Dec. 21, 1979), and the USDA has a matter of policy adopted the FDA's definition of the term. *See In Re: Castleberry's Food Co.*, FMIA No. 36 at p. 10 (USDA 1981); Food Labeling: Tentative Positions of Agencies, 44 Fed.Reg. 75990 (Dec. 21, 1979); Affidavit of Robert G. Hibbert, Director of Standards and Labeling Division, Meat

3. The FDA has issued its food labeling regulations under both the Fair Package Labeling Act ("FPLA") and the FDCA. *See* 21 C.F.R. Part 101; 38 Fed.Reg. 20702 (Aug. 2, 1973). The FPLA provides labeling requirements that are similar to the misbranding provisions set forth in the FDCA. *Compare* 15 U.S.C. § 1453 *with* 21 U.S.C. § 343. While the FPLA contains an express preemption provision, 15 U.S.C. § 1460, plaintiff does not suggest that the New York regulations are preempted under that statute.

and Poultry Inspection Technical Service, United States Department of Agriculture sworn to on December 9, 1983 at ¶ 2-3; Affidavit of Donald Houston, Administrator of the Food Safety Inspection Service, United States Department of Agriculture sworn to on February 2, 1984 at ¶ 4. Violators of the FMIA and the PPIA are subject to both civil and criminal sanctions. 21 U.S.C. §§ 461 & 467 poultry); 21 U.S.C. §§ 672-676 (meat). Both Acts have an express preemption provision allowing the states to exercise concurrent jurisdiction in enforcement of the Acts but prohibiting the states from imposing "[m]arking, labeling, packaging, or ingredient requirements in addition to or different than, those made under" the respective statutes. 21 U.S.C. §§ 467e & 678.[4]

Section 63 of the New York Agriculture and Markets Law was enacted on July 22, 1982, and became effective one year later.[5] The statute requires, in part, that products deemed under New York law to be imitation cheese or imitation cheese food bear the word "imitation" on their

4. Both preemption provisions provide in part:

> Marking, labeling, packaging, or ingredient requirements . . . in addition to, or different than, those made under this chapter may not be imposed by any State . . . with respect to articles prepared at any official establishment in accordance with the requirements under this chapter, but any State . . . may, consistent with the requirements under this chapter exercise concurrent jurisdiction with the Secretary . . . for the purpose of preventing the distribution of . . . any such articles which are adulterated or misbranded . . . . This chapter shall not preclude any State . . . from making requirement or taking other action, consistent with this chapter, with respect to any other matters regulated under this chapter.

5. A 1983 amendment changed the size of the required labels from one third the size of the brand name to letters of equal size. N.Y.Agric. & Mkts. Law § 63 (McKinneys Supp.1983) *as amended by* 1983 N.Y.Laws ch. 617, § 1; *see also* n. 6, *infra*.

labels in letters of the same color, on a contrasting background, and of equal size as the letters of the brand name or product designation whichever is larger.[6] The statute further provides that service food establishments which offer products containing imitation cheese or imitation cheese food must (a) post a sign on the premises which states the names of the foods containing imitation cheese or imitation cheese food in block letters at least three inches in height against a contrasting background; (b) state on their menus the names of the products containing imitation cheese or imitation cheese food immediately after the product designation on the menu in letters of equal size; and (c) conspicuously label any container used by consumers which contains imitation cheese or imitation cheese food product.[7]

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6. The labeling provisions of the statute require that:

The word "imitation" must appear on the labels of imitation cheese and imitation cheese food in letters of the same color, same contrasting background, and of equal size as the brand name or product designation, whichever is larger. "Imitation" must immediately precede the brand name or printed product designation, without intervening printed or graphic matter, everytime the brand name or product designation appears on the label. Labels of products containing imitation cheese or imitation cheese food must bear the words "contains imitation cheese" or "contains imitation cheese food" immediately preceding the name of the food. The letters in the quoted phrase must be in the same color, on the same contrasting background, and of equal size as the letters in the product designation.

7. The sign and menu posting provisions require that:

Establishments which offer products containing imitation cheese or imitation cheese food for carryout or on premises consumption must prominently post a sign which state the product designation of the food followed immediately by the words "contains imitation cheese" or "contains imitation cheese food." The letters on the sign must be in block letters at least three inches high in height and on a contrasting background which can be

(footnote continued on next page)

Appendix B

The Commissioner of the New York Department of Agriculture and Markets issued final regulations implementing the statute which were to become effective on February 1, 1984. Pending the outcome of this litigation, however, the Commissioner has agreed not to enforce the statute and its regulations. The regulations define "imitation" cheese as "any food which is similar in texture, color, flavor, taste, and appearance" to cheese. 1 NYCRR §§ 18.1 (c) & (d). Thus, the New York regulations require the word imitation on nutritionally equivalent or superior substitute cheese products instead of the federal requirement of the word "substitute" or other common or descriptive term. This conflict in definition as well as the additional labeling, sign posting and menu notification requirements form the basis of plaintiff's claims.

STANDING

Defendants' initial argument that GMA lacks standing to bring this action is without merit.[8] The standing of an

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easily read by consumers under normal conditions of purchase.

Service food establishments which offer any product containing imitation cheese or "imitation cheese food product" must state on the menu that the product "contains imitation cheese" or "contains imitation cheese food." The quoted phrase must immediately follow the product designation on the menu, and it must be in letters of equal size and on a contrasting background.

Service food establishments which place imitation cheese or "imitation cheese food product" on tables, or otherwise make it available for use by customers, must conspicuously label the container of such product "imitation cheese" or "imitation cheese food product."

8. In their answer, the Commissioner also suggests that plaintiff's claims are barred by the eleventh amendment. The eleventh amendment simply does not prevent the declaratory and injunctive relief sought by GMA, *see Edelman v. Jordan,* 415 U.S. 651, 94 S.Ct. 1347, 39 L.Ed.2d 662 (1974), nor does it prevent an award of attorneys fees under 42 U.S.C. § 1988 in a proper case. *Hutto v. Finney,* 437 U.S. 678, 98 S.Ct. 2565, 57 L.Ed.2d 522 (1978).

association to assert the rights of its members is well established. *See Hunt v. Washington Apple Advertising Comm'n,* 432 U.S. 333, 97 S.Ct. 2434, 53 L.Ed.2d 383 (1976); *National Motor Freight Ass'n v. United States,* 372 U.S. 246, 83 S.Ct. 688, 9 L.Ed.2d 709 (1963). In *Hunt,* the Court stated that an association may have standing if:

> The association . . . allege[s] that its members, or any one of them, are suffering immediate or threatened injury as a result of the challenged action of the sort that would make out a justiciable case had the members themselves brought suit . . . . So long as this can be established, and so long as the nature of the claim and of the relief sought does not make the individual participation of each injured party indispenable to proper resolution of the cause, the association may be an appropriate representative of its members entitled to invoke the court's jurisdiction.

432 U.S. at 342-43, 97 S.Ct. at 2440-41, quoting *Warth v. Seldin,* 422 U.S. 490, 511, 95 S.Ct. 2197, 2211, 45 L.Ed.2d 343 (1975).

Plaintiff's members are engaged in the business of producing, selling and distributing food products throughout the United States. Affidavit of Sherwin Gardner, Vice President, Science and Technology, GMA, sworn to January 17, 1984. Implementation of the New York statute will have an immediate and direct effect on them. *See e.g.,* Affidavit of Thomas Brennan, District Manager of Industrial Products, Schreiber Foods, Inc. sworn to on January 12, 1984. Moreover, since "neither the claims asserted, nor the relief requested, requires the participation of individual members in the lawsuit," *Hunt,* 432 U.S. at 343,

97 S.Ct. at 2441, the individual members themselves are not indispensable parties. Under the *Hunt* standard, therefore, GMA has standing to assert the rights of its members in contesting the labeling provisions of the New York statute.

Further, GMA—as the representative of manufacturers and distributors of food products—is a proper party to press a challenge to the sign and menu posting requirements of the New York statute even though those provisions apply only to food service establishments. Uncontroverted affidavits submitted by GMA fully support a finding that its members will suffer direct and immediate harm in the form of lost sales as the result of the sign and menu posting requirements of the New York statute. Affidavit of Thomas Brennan, District Manager of Industrial Products, Schreiber Foods, Inc. sworn to on January 12, 1984; Affidavit of George W. Cawman, Vice President of Marketing, Schreiber Food, Inc. sworn to on December 13, 1983; Affidavit of Olindo DiFrancesco, President, Olindo's Food, Inc. sworn to on January 17, 1984. As indicated by the affidavit of Thomas Brennan, *supra*, the likely consequence of the sign and menu posting requirements is that food service establishments will purchase only natural cheese products in order to avoid compliance with the statute and the stigma associated with the term "imitation." I find therefore that under the *Hunt* standard, GMA also has standing to challenge the sign and menu posting requirements of Section 63.

Appendix B

PREEMPTION

Both the FDA and the USDA agree that the sign and menu posting requirements of the New York statute are not preempted by the FDCA, FMIA or the PPIA. GMA's challenge to those provisions under the Commerce Clause will be addressed in a later section. The more difficult matter raised by the New York Imitation Cheese Statute is whether the labeling regulations are preempted by the respective federal statutes under the Supremacy Clause of the United States Constitution. The Commissioner argues that the federal regulations govern only the labeling of imitation cheese and do not extend to the labeling of food products which merely contain artificial cheese. Thus, defendants contend that the state is not preempted from issuing its own regulations in the related field.

A. *The Federal Meat and Poultry Acts*

(1) The Preemptive Effect of the Federal Regulations

Both the FMIA and the PPIA explicitly address the labeling and ingredient requirements for all federally inspected meat and poultry food products transported in interstate commerce. In fact, the USDA is now considering proposed regulations on the labeling of meat and poultry food products containing cheese substitutes and a revised standard of identity for meat-topped pizza which would include a consideration of imitation cheese. Affidavit of Robert Hibbert, *supra,* at ¶ 6; 48 Fed.Reg. 35654-59 (Aug. 5, 1983). Each statute provides that while the

state may exercise concurrent jurisdiction in enforcing the federal regulations, it may not impose labeling requirements that are "in addition to, or different than, those made under" the respective acts. 21 U.S.C. §§ 678 & 467e. The New York regulations which require meat and poultry products to be labeled in a manner other than that prescribed by the USDA, are "in addition to or are different than" the federal regulations in contravention of the express preemption provision of the FMIA and the PPIA. *See Jones v. Rath Packing Co.*, 430 U.S. 519, 97 S.Ct. 1305, 51 L.Ed.2d 604 (1977) (California practice of determining average net weight of meat food packages different from federal law is preempted; *Armour & Co. v. Ball*, 468 F.2d 76 (6th Cir.1972), *cert. denied*, 411 U.S. 981, 93 S.Ct. 2267, 36 L.Ed.2d 957 (1973) (Michigan law establishing standards of identity for sausage different from federal standards is preempted). The preemption provision found in the PPIA, in fact, was a Congressional response to a decision of the Second Circuit upholding a New York statute which imposed state labeling requirements for turkeys which were in addition to the labeling requirements of federal law. *See Swift & Co. v. Wickham*, 364 F.2d 241 (2d Cir.1966), *cert. denied*, 385 U.S. 1036, 87 S.Ct. 776, 17 L.Ed.2d 683 (1967); Pub.L. 90-492 (Aug. 18, 1968) (adding to 21 U.S.C. § 467e); 90 H.Rep. No. 1333, 90th Cong.2d Sess. *reprinted in* 1968 U.S.Code Cong. & Ad.News 3426, 3427 (extending federal regulation to ensure state requirements at least equal to federal).

Moreover, the USDA has unequivocally stated that lebels consistent with New York's regulatory scheme will not be approved by the agency if the product to be labeled

is not nutritionally inferior to the product for which it substitutes. Affidavit of Donald Houston, Administrator of the Food Safety Inspection Service, United States Department of Agriculture, sworn to Feb. 2, 1984 at ¶ 8; Affidavit of Robert G. Hibbert, Director of Standard and Labeling Division, Meat and Poultry Inspection Technical Services, Food Safety and Inspection Service, United States Department of Agriculture sworn to Dec. 9, 1983 at ¶¶ 7 & 8. Thus, as to those meat and poultry products containing cheese substitutes which are subject to federal inspection and labeling provisions under the FMIA and the PPIA, the New York provisions are expressly preempted.

(2) Validity of the Federal Regulations

In apparent recognition that the New York statute is preempted, the Commissioner attacks the validity of the USDA's "imitation policy" asserting that the USDA policy of applying the FDA's definition of imitation is procedurally defective because there was no formal notice and comment period as required by the Administrative Procedure Act ("APA"), 5 U.S.C. § 522, *et seq.* The distinction between a "rule" as defined in 5 U.S.C. § 551, which must be published with a notice and comment period, and "a general statement of policy" or an "interpretative rule" which are each excluded from the requirements of the APA, 5 U.S.C. § 553(b)(3)(A), "is enshrouded in considerable fog." *Noel v. Chapman,* 508 F.2d 1023, 1030 (2d Cir.), *cert. denied,* 423 U.S. 824, 96 S.Ct. 37, 46 L.Ed.2d 40 (1975).

Appendix B

Faced with a similar problem, the District of Columbia Circuit Court of Appeals distinguished the three terms in *Pacific Gas & Elec. Co. v. FPC*, 506 F.2d 33 (D.C.Cir.1974), and held that an order of the Federal Power Commission establishing a priority schedule for curtailing delivery of natural gas in time of shortage was a general statement of policy. *Id.* at 41. The Court explained that "[a] general statement of policy is the outcome of neither rulemaking nor an adjudication, it is neither a rule nor a precedent but is merely an announcement which the agency hopes to implement in future rulemakings or adjudications." *Id.* at 38. "Interpretative rules are similar in some respects to general statements of policy . . . An interpretative rule expresses the agency's view of what another rule, regulation, or statute means." 506 F.2d at 37 n. 14. On the other hand, the court found that a rule "establishes a standard of conduct which has the force of law." *Id.* at 38. It memorializes a binding norm not subject to challenge by individual parties. In holding that the FPC's order was a statement of general policy, the Court noted that the Commissioner intended "to establish the policy by proceeding through individual adjudications." *Id.* at 41.

Applying that standard to this case, I find that the USDA's imitation food policy is more akin to a statement of general policy or an interpretative rule than to a rule which requires formal notice and comment proceedings. Because the policy is merely an interpretation of a statutory term not defined by the relevant statute, it may be an interpretative rule. I believe, however, that the policy is a statment of the general policy of the agency pending

the outcome of rulemaking proceedings. After reviewing the FDA's 1973 definition of imitation, the USDA stated in 1979 in the Federal Register that the tentative position of the agency was to follow the 1973 FDA regulations pending further comment and formal rulemaking proceedings. 44 Fed.Reg. 76008 (Dec. 21, 1979). The USDA expressly adopted the policy in 1981 through the adjudicatory process in *In Re Castleberry's Food Co.*, FMIA Docket No. 36 (Sept. 18, 1981) which was made available to the public in accordance with 5 U.S.C. § 552(a)(2).[9] Formal rulemaking proceedings are presently pending. Moreover, the statutory scheme expressly permits the implementation of the policy on a case by case basis by requiring that all labels be individually approved by the agency prior to shipment in interstate commerce and that challenges to USDA labeling decisions to be made through individual adjudications. *See* 21 U.S.C. §§ 607(d) & (e); 21 U.S.C. §§ 457(c) & (d). Thus, it appears to me that the USDA's adoption of the FDA's definition of "imitation" is merely

9. Section 552(a)(2) of the Administrative Procedure Act provides in pertinent part that:

> Each agency, in accordance with published rules, shall make available for public inspection and copying—
>
> (A) final opinions . . . made in the adjudication of cases . . .
>
> (B) those statements of policy and interpretations which have been adopted by the agency and are not published in the Federal Register . . .
>
> A final order, opinion, statement of policy, interpretation, or staff manual or instruction that affects a member of the public may be relied on, used, or cited as precedent by an agency against a party other than the agency only if—
>
> (i) it has been indexed and either made available or published as provided by this paragraph; or
>
> (ii) the party has actual or timely notice of the terms thereof.

a statement of general policy that is not procedurally invalid on the grounds that there was no formal rulemaking. *See also* 5 U.S.C. § 553(b)(3)(A); *Noel v. Chapman,* 508 F.2d 1023 (2d Cir.), *cert. denied,* 423 U.S. 824, 96 S.Ct. 37, 46 L.Ed.2d 40 (1975); *Continental Oil Co. v. Burns,* 317 F.Supp. 194 (D.Del.1970); K. Davis, Administrative Law Treatise §§ 7:4 & 7:5 (2d ed. 1979).

Even if I were to find the federal regulation invalid, the preemption provisions alone appear to preclude state regulation of meat and poultry food products containing imitation cheese. New York's regulations requiring the term imitation on all labels are "in addition to" the federal standard and are thus, expressly preempted. Besides his challenge to the procedural validity of the regulation, the Commissioner raises a question as to the substantive validity of the definition of imitation as adopted by the FDA. I turn to this argument in the following section in addressing preemption under the FDCA.

B. *The Federal Food Drug and Cosmetic Act.*

(1) The Preemptive Effect of the Federal Regulations

The regulatory scheme promulgated under the FDCA likewise preempts the labeling of food products which resemble or substitute for cheese or which contain cheese substitues. The Commissioner, however, argues that the FDCA does not preempt New York's statute because, unlike the FMIA and the PPIA, the FDCA contains neither explicit labeling provisions applicable to artificial cheese nor an express preemption provision. In support, the

Commissioner relies on *Corn Products Refining Co. v. Eddy,* 249 U.S. 427, 39 S.Ct. 325, 63 L.Ed. 689 (1919), in which the Supreme Court held that, absent federal action, the state retains its right to provide for adequate safeguards against deception in the sale of food products. The Commissioner's argument, however, ignores the preemptive effect of the federal regulations that implement the FDCA. When Congress has given an agency the authority to act, the resulting "federal regulations have no less preemptive effect than federal statutes." *Fidelity Sav. & Loan Ass'n v. De La Cuesta,* 458 U.S. 141, 153, 102 S.Ct. 3014, 3022, 73 L.Ed.2d 664 (1981). Consequently, the issue is whether the regulatory scheme, read in conjunction with the federal statute, has impliedly preempted the field.

The Supreme Court recently discussed the standard I must apply in determining whether state laws are preempted by federal law in *Silkwood v. Kerr-McGee,* —— U.S. ——, 104 S.Ct. 615, 78 L.Ed.2d 443 (1984). The Court explained that:

> state law can be preempted in either of two general ways. [a.] If Congress evidences an intent to occupy a given field, any state law falling within that field is preempted. . . . [b.] If Congress has not entirely displaced state regulation over the matter in question, state law is still preempted to the extent that it actually conflicts with federal law . . . or where state law stands as an obstacle to the accomplishment of the full purpose and objectives of Congress.

Id. at 621 (citations omitted). Plaintiff argues that the New York regulations are invalid under either analysis. I will address each argument in turn.

Appendix B

(a) Congressional Intent to Occupy the Field

GMA contends that the FDCA manifests a Congressional desire to comprehensively regulate the labeling of food products shipped in interstate commerce leaving no room for state regulation. In considering similar arguments, the Supreme Court has cautioned that "federal regulation of a field of commerce should not be deemed preemptive of state regulatory power in the absence of persuasive reasons —either that the nature of the regulated subject matter permits no other conclusion or that Congress has unmistakably so ordained." *Florida Lime & Avocado Growers v. Paul,* 373 U.S. 132, 142, 83 S.Ct. 1210, 1217, 10 L.Ed.2d 248 (1963). The test for determining regulatory preemption is whether the agency intended its regulations to supersede state law. *Fidelity Federal Sav. & Loan Ass'n v. De La Cuesta,* 458 U.S. 141, 154, 102 S.Ct. 3014, 3022, 73 L.Ed.2d 664 (1981).

The principal focus of the FDCA is to "keep impure and adulterated [food and] drugs out of the channels of commerce." *62 Cases of Jam v. United States,* 340 U.S. 593, 596, 71 S.Ct. 515, 95 L.Ed. 566 (1951). The federal labeling provisions in question here were specifically "designed to protect the public from inferior foods resembling standard products but marketed under distinctive names. *See* S.Rep. No. 361, 74th Cong. 1st Sess. 8-11." *Id.* at 600, 71 S.Ct. at 520. Nothing in the FDA regulations necessarily reflects an intention by the FDA to displace the imitation food labeling requirements of a state. The statute itself does not reveal an unmistakable intention to oust state regulation. Moreover, plaintiff has not demonstrated

that there is an overwhelming need for national uniformity or that the statute was designed to create such uniformity. Thus, there is no persuasive reason for me to find that Congress intended to occupy the field. *Cf. Swift & Co. v. Wickham,* 364 F.2d 241, 244 (2d Cir.1966) (the court, in dicta, notes that the FDCA does not preempt state regulation), *cert. denied,* 385 U.S. 1036, 87 S.Ct. 776, 17 L.Ed.2d 683 (1967).

(b) Actual Conflict

In my view, however, the state regulations are preempted because they are in conflict with the federal regulations. In *Ray v. Atlantic Richfield Co.,* 435 U.S. 151, 158, 98 S.Ct. 988, 994, 55 L.Ed.2d 179 (1978), the Supreme Court explained that:

> A conflict will be found "where compliance with both federal and state regulations is a physical impossibility . . .," *Florida Lime & Avocado Growers, Inc. v. Paul,* 373 U.S. 132, 142-143 [83 S.Ct. 1210, 12172-1218, 10 L.Ed.2d 248, 98 S.Ct. 988, 994, 55 L.Ed.2d 179] (1963), or where the state "law stands as an obstacle to the full purposes and objectives of Congress." *Hines v. Davidowitz,* 312 U.S. 52, 67 [61 S.Ct. 399, 404, 85 L.Ed. 581] (1941); *Jones v. Rath Packing Co., supra,* [430 U.S.] at 526, 540-541 [97 S.Ct. at 1310, 1317]. *Accord, De Canas v. Bica,* 424 U.S. 351, 363 [96 S.Ct. 933, 940, 47 L.Ed.2d 43] (1976).

The New York regulations require that all cheese substitutes or food containing cheese substitutes be labeled "imitation" even though the FDA would require that only "nutritionally inferior" products be labeled with the term. The FDA expressly found that labeling all substitutes as

imitation is misleading and confusing to consumers. 38 Fed.Reg. 2138 (Jan. 19, 1973). Instead, the federal regultaions require nutritional equivalent products to be labeled by a common or descriptive term, e.g., mozzarella cheese substitute. The New York standard as applied to nutritionally equivalent or superior products is contrary to the federal standard and products labeled as such would be deemed misbranded under the federal statute. *See* 21 U.S.C. § 434(c3); 21 F.F.R. § 101.3(e); Affidavit of Robert Hibbert, *supra* at ¶ 7 & 8; Affidavit of Donald Houston, *supra,* at ¶ 8. Thus, if a manufacturer complies with the New York statute, the manufacturer would, at the same time, violate the federal regulations and would therefore be subject to sanctions under the federal statute for misbranding. In short, compliance with both regulations is impossible.

The Commissioner suggests that the New York regulations are consistent with federal regulations because the language of the regulations do not preclude "a nutritionally equivalent" food product from being labeled an "imitation." Although the FDA has determined that some nutritionally equivalent products may be designated as "imitation," 38 Fed.Reg. 20702-703 (Aug. 2, 1973), the agency has also determined the specific circumstances under which that can occur. It has stated that:

> A manufacturer or distributor may label a substitute food which is not nutritionally inferior to the traditional food as an imitation *if he concludes that the product is inferior in some other way and if the use of the term is not misleading.*

Id. (emphasis added). Thus, any question as to when use of the label "imitation" is required is foreclosed by the FDA's regulations.

In addition, the New York regulations frustrate FDA's dual purpose of encouraging the development of nutritious foods and of informing the public of "the actual characteristics and properties of a new food product." *See* 38 Fed.Reg. 2138 (Jan. 19, 1973); *accord,* 38 Fed.Reg. 20702 (Aug. 2, 1973). The FDA has expressly rejected the Commissioner's *per se* application of the term "imitation" to all food substitutes because the term connotes inferiority and would thereby discourage the development of nutritionally superior products in contravention of Congressional intent in passing the FDCA. 38 Fed.Reg. 2138 (January 18, 1973). Moreover, the FDA found that the indiscriminate use of "imitation" on all foods leads to consumer confusion which the FDCA was designed to prevent. Thus, the state regulation interferes with the "accomplishment and execution of the full purposes and objectives" of the agency's regulations. *See Ray v. Atlantic Richfield Co.,* 435 U.S. 151, 158, 98 S.Ct. 988, 994, 55 L.Ed. 2d 179 (1977) citing *Hines v. Davidowitz,* 312 U.S. 52, 67 61 S.Ct. 399, 404, 85 L.Ed. 581 (1941). Under these circumstances, where the state regulations directly conflict with federal law and in fact, stand as an obstacle to the accomplishment of the purpose of the federal law, the state regulations are preempted by the federal regulatory scheme.

Appendix B

(2) Validity of the Federal Definition of Imitation

The Commissioner's primary argument in support of the state regulations is that the FDA and the USDA are not enforcing the respective statutes as Congress intended. None of the pertinent federal statutes define the term "imitation."[10] The Commissioner argues, however, that judicial precedent construing the term requires the federal agencies to adopt a definition which comports with the term's ordinary and plain meaning. This, defendant contends, is precisely what New York has done in requiring all artificial cheese products that resemble traditional cheese in taste, smell, texture and apperance to be labeled imitation. Because the agencies have ignored this precedent, the Commissioner argues that the FDA's definition of imitation is contrary to the FDCA and is invalid.

In *Federation of Homemakers v. Schmidt,* 539 F.2d 740 (D.C.Cir.1976), the District of Columbia Circuit Court of Appeals deferred to the expertise of the FDA in promulgating its definition of imitation and found that the regulation which takes into account only nutritional inferiority

10. The Filled Milk Act, 21 U.S.C. §§ 61-64, in particular, lends little support to the Commissioner's position. The statute, which was enacted in 1923 and held unconstitutional in *Milnot v. Richardson,* 350 F.Supp. 221 (D.Ill.1972), precluded any person from manufacturing or shipping in interstate commerce any item of "filled milk". 21 U.S.C. § 61. "Filled milk" was defined as any milk . . . "to which has been added . . . any fat or oil other than milk fat, so that the resulting product is in imitation or semblance of milk. . . ." 21 U.S.C. § 61(c). The statute did not apply to the labeling of food products. Neither the Act nor the few cases construing it expressly define the term "imitation." *See e.g., Carolene Products v. United States,* 323 U.S. 18, 65 S.Ct. 1, 89 L.Ed. 15 (1944). Rather, the statute merely presented an absolute ban on all substitute milk products whether or not the product was an imitation or was informatively labeled.

is "well within the zone of reasonableness required of agency rulemaking." 539 F.2d at 743-744. The Eighth Circuit adopted the reasoning of the Court in *Homemakers* and again upheld the regulation in *National Milk Producers' Federation v. Harris,* 653 F.2d 339 (8th Cir.1981). The Commissioner challenges the reasoning of each decision on the ground that the Courts improperly deferred to the agency's interpretation of a statutory term. I disagree. Certainly, statutory interpretation is a question of law which, as a general rule, is freely reviewable. Nevertheless, "the interpretation of an agency charged with the administration of a statute is entitled to substantial deference," *Blum v. Bacon,* 457 U.S. 132, 141, 102 S.Ct. 2355, 2361, 72 L.Ed.2d 728 (1981), unless the agency's interpretation is "contrary to the indications of the statute itself." *SEC v. Sloan,* 436 U.S. 103, 117, 98 S.Ct. 1702, 1711, 56 L.Ed.2d 148 (1977).

The Commissioner cites no legislative authority which indicates that Congress intended to adopt a standard for imitation that requires consideration of texture, color, flavor, taste and apperance. My own research discloses none. Cases construing the term "imitation" prior to the issuance of the 1973 regulations, however, do tend to support the Commissioner's position. *See e.g., 62 Cases More (or Less) of Jam v. United States,* 340 U.S. 593, 599-600, 71 S.Ct. 515, 519-520, 95 L.Ed. 566 (1951); *United States v. 651 Cases, More or Less, of Chocolate Chil-Zert,* 114 F. Supp. 430, 432 (N.D.N.Y.1953). In each of these cases, the Courts struggled with the definition of the term "imitation" and considered whether the substitute food product resembled the traditional food in terms of taste, smell,

texture and appearance. The only consistent holding to be extrapolated from the cases is that the term "connotes inferiority". *62 Cases of Jam v. United States,* 340 U.S. at 599, 71 S.Ct. at 519; *United States v. 651 Cases, . . . of Chocolate Chil-Zert,* 114 F.Supp. at 432.

The FDA regulation is not to the contrary. As a practical matter, the agency must consider taste, smell, texture and appearance in order to make the preliminary determination that the product is a substitute for or resembles a traditional food. *See In Re: Castleberry's Food Co.,* FMIA No. 36 (USDA 1981). Moreover, the FDA's definition preserves the notion of inferiority. The imitation standard merely defines inferiority in terms of a product's nutritional content and requires that a product which is nutritionally inferior to the food it resembles be labeled imitation. Nutritionally equivalent products may only be labeled imitation if the product is inferior to the traditional food for some other reason. The agency's abandonment of taste, smell and appearance as the test of inferiority in favor of a nutritional equivalency standard because the former test was too subjective is well within the discretion granted to it by Congress. *See Weinberger v. Hynson, Wescott & Dunning, Inc.,* 412 U.S. 609, 93 S.Ct. 2469, 37 L.Ed.2d 207 (1973); *CIBA-Geigy Corp. v. Richardson,* 446 F.2d 466, 468 (2d Cir.1971).

Furthermore, Congress appears to be satisfied with the FDA's standard for imitation because, although it has twice amended the FDCA misbranding provisions since the regulations were issued, Pub.L. 94-278 (1976) (adding § 343(a)(1) and (2)); Pub.L. 95-203 (1978) (adding §§ 343(*o*) & (p)), Congress has not acted to amend FDA's

imitation standard. *See United States v. Rutherford*, 442 U.S. 544, 554, 99 S.Ct. 2470, 2476, 61 L.Ed.2d 68 (1978) (that Congress has not acted to correct any misperception of its statutory objectives on an issue of public importance weighs in favor of deference to the agency's construction).

The FDA's regulations defining "imitation" represent a carefully considered effort to construe a statutory term not defined by Congress. The notice of proposed rulemaking published in 1973 stated that the term must be defined in light of its common understanding and must take into account recent advances in the industry which have developed food substitues that are not inferior to the products for which they substitute. 38 Fed.Reg. 2138 (Jan. 19, 1973). The agency recognized that applying the term "imitation" to nutritionally equivalent or superior foods would be misleading to the consumer because traditional notions of the term suggest inferiority. *Id.* In August of 1983, after a notice and comment period, the FDA reaffirmed its existing definition of "imitation," 48 Fed.Reg. 37665 (Aug. 19, 1983), and noted that consumer recent surveys supported a finding that the term "imitation" connotes an inferior product. *Id.* at 37665-66. As the Court stated in *Homemakers*, "the new regulation successfully reconciles the need to alert the public to inferior products with the proscription in subsection 343(a) against false or misleading labels." *Federation of Homemakers v. Schmidt*, 539 F.2d 740, 743 (D.C.Cir.1976).

In arguing that the Court in *Homemakers* improperly deferred to the agency's expertise, defendants urge me to follow *Swift & Co., Inc. v. Walkley*, 369 F.Supp. 1198 (S.D. N.Y.1973) (Weinfeld, J.). In *Swift*, the court denied a

motion by a manufacturer of imitation frankfurters to enjoin the state from requiring a meat product bearing a USDA approved label to be labeled "imitation frankfurter." Judge Weinfeld did not address the FDA's recently issued "nutritionally inferior" standard for imitation food. Instead, the court reasoned that the USDA's admitted disregard of the statute did not prevent the state from exercising its concurrent jurisdiction to enforce it. *Id.* The case does not warrant a different result here. The FDA has not refused to enforce the statute nor, as the result here shows, has it issued standards contrary to the FDCA. I believe that the Eighth and District of Columbia Circuits properly deferred to the agency's expertise and find that the regulation as issued is valid.

COMMERCE CLAUSE

As a second ground for enjoining Section 63, plaintiff argues that the statute imposes an impermissible burden on interstate commerce. In deciding whether the state requirements unconstitutionally burden interstate commerce the threshold inquiry is whether the state regulation operates even-handedly between intrastate and interstate commerce to effectuate a legitimate local public interest. *Hughes v. Oklahoma,* 441 U.S. 322, 332, 336, 99 S.Ct. 1727, 1734, 1736, 60 L.Ed.2d 250 (1979); *Pike v. Bruce Church, Inc.,* 397 U.S. 137, 142, 90 S.Ct. 844, 847, 25 L.Ed.2d 174 (1969). In this case, I have no doubt that the regulations operate even-handedly to the extent that all foodstuffs containing imitation cheese are subject to the menu and sign posting requirements. The question thus devolves to

whether, despite the even-handed operation of the regulations, the burden of interstate commerce is excessive in relation to the putative local benefits. *Pike v. Bruce Church, Inc.*, 397 U.S. at 142, 90 S.Ct. at 847. Because I have already found that the labeling provisions of the New York statute are invalid, I need only consider whether the burden the sign and menu posting provisions place on interstate commerce is excessive in light of the putative local benefits.[11]

A. *Asserted Local Benefits*

The New York regulations are intended to promote a legitimate and, indeed, laudible purpose. The statute was enacted to promote informed consumerism and fair competition by preventing fraud and deception in the marketing of alternative cheese products. Regulation of the production of foodstuffs market has traditionally been a matter of local concern. *Florida Avacado and Lime Growers v. Paul*, 373 U.S. 132, 83 S.Ct. 1210, 10 L.Ed.2d 248 (1963);

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11. The Commissioner's contention that 21 U.S.C. § 25, which was enacted in 1902, removes the Commerce Clause issue from this case is baseless. The statute provides, in part that:

> All articles known as . . . imitation cheese, or any substance in the semblance of butter or cheese not the usual product of the dairy and not made exclusively of pure and unadulterated milk or cream, transported into any State . . . and remaining therein for use, consumption, sale or storage therein, shall, upon the arrival within the limits of such State . . . be subject to the operation and effect of the laws of such State . . . .

21 U.S.C. § 25. One of the few cases to construe the statute make it clear that Congress, in passing 21 U.S.C. § 25, intended to preserve to the states their traditional police powers of protecting its citizens from adulterated foods. *Cloverleaf Co. v. Patterson*, 315 U.S. 148, 62 S.Ct. 491, 86 L.Ed. 754 (1941). As the Court noted in *Cloverleaf*, however, 21 U.S.C. § 25 does not permit a state to act in a way "inconsistent with federal legislation." I should also note that the Commissioner has cited no authority, except the statute itself, for this broad proposition.

Appendix B

American Meat Institute v. Ball, 550 F.Supp. 285, 287 (W.D.Mich.1982). So, too, has been the protection of consumers from deception and fraud. *Savage v. Jones,* 225 U.S. 501, 32 S.Ct. 715, 56 L.Ed. 1182 (1912). The state clearly has a legitimate interest in protecting purchasers from the adverse consequences of unknowingly consuming inferior cheese substitutes. The sign and menu regulations which would require the labeling of inferior products as imitation would effectuate that purpose.

The statute as applied to nutritionally equivalent and superior cheese products, however, reaches beyond that limited interest and attempts to prevent consumer deception in the consumption of cheese food products that will not affect the consumer's nutritional well-being. Nutritionally equivalent and superior cheese substitutes have nutritional, dietary, medical, religious and economic advantages not found in traditional cheese products. *See* Affidavit of Dr. Robert G. Bursey, Manager, Nutrition Research, Kraft, Inc., sworn to January 11, 1984; T. Graff, Report of Economic Impact of Imitation Cheese, August, 1982, Exhibit 2 to Plaintiff's Reply Brief; Affidavit of R.W. Nicholas, Director, Institutional Food Products, Anderson Clayton Foods, sworn to January 11, 1984. The blanket labeling of all substitutes as "imitation" does little to convey to the consumer information as to the ingredients, nutritional value or effect on the consumer's health. In fact, the blanket labeling requirement may itself cause consumer confusion because consumers equate the term "imitation" with inferior products and because all other food products are labeled under the federal standard. *See e.g.,* Affidavit of Thomas Blaisdell Smith, Director of Government Af-

fairs, Public Voice for Food and Health Policy sworn to January 10, 1984.

As an example, in *American Meat Institute v. Ball*, 550 F.Supp. 285 (W.D.Mich.1982), *aff'd on other grounds*, 724 F.2d 45 (6th Cir.1984), a Michigan state statute requiring that meat products not meeting Michigan standards be accompanied by a placard stating that such products "do not meet Michigan's high ingredient standards but do meet lower federal standards," was found to have little, if any, local public benefit for similar reasons. In finding that the statute promoted no legitimate state interest, the court stated that "the Michigan placard does not rectify any lack of meaningful information, but merely substitutes one form of incomplete information for another." *Id.* at 292. I likewise believe that the menu and sign posting requirements as applied to all substitute cheese products do little to effectuate the purpose of the statute and thus, have limited value to the public.

B. *Burden on Interstate Commerce*

As a practical matter, food service establishments will have no method of determining whether the product they serve is an imitation within the meaning of the state statute. The only notice a restauranteur or store owner may have of what is being served is through the packaging of the product by the manufacturer yet the manufacturer is not required to comply with the labeling provisions of the statute. Under these circumstances, the retailer has few alternatives; he will be unable to comply with the statute, will opt in favor of serving only natural cheese, or will insist that

the manufacturer provide information sufficient to insure the retailers compliance with the statute. If he chooses either of the latter alternatives, I am faced with the question of whether, despite the putative local benefits, the statute places an excessive burden on interstate commerce.

There is no question that the implementation of the New York regulations will have an immediate and direct impact on interstate commerce. The State regulations will necessarily increase the costs of doing business in New York for plaintiff's members as they will incur additional expenses in providing necessary information to retailers. *See* Exhibits 7-15 to Plaintiff's Reply Brief. Producers, desirous of continuing to do business in New York, will be compelled to provide information to the retailer in addition to that required by federal law which will be limited to use in New York. Moreover, as the affidavit of Thomas Brennan, *supra,* demonstrates, GMA's members will suffer direct loss in the form of lost sales if the retailer chooses to serve only natural cheese. *See also* Affidavit of George W. Cawman, *supra.* The affidavit of Olinda DiFransesco, *supra,* indicates that because of the anticipated enforcement of the New York statute, some manufacturers have already suffered a loss of sales.

Furthermore, there are less burdensome means of serving the same objectives. Inasmuch as the federal government has found it possible to protect consumers from misleading packaging through its ingredients requirements, it cannot be said that less burdensome measures are not available to New York. In view of the questionable local benefits to be achieved by the regulations, I find that the New

York sign and menu posting provisions impose an unacceptable burden on interstate commerce.

Because I have ruled that the labeling provisions of Section 63 of the New York Agriculture and Markets Law as interpreted by the Commissioner's regulations are preempted by federal regulations and that the menu and sign posting provisions of the statute place an unreasonable burden on interstate commerce, I need not address plaintiff's equal protection or state law claims.

For the reasons stated above, New York's Imitation Cheese Statute, N.Y. Agric. & Mkts. Law § 63 (McKinneys Supp. 1983), and its implementing regulations, 1 NYCRR 18, are unconstitutional and a permanent injunction enjoining defendants from enforcing those provisions is granted. Plaintiff's request for attorneys fees is denied.

APPENDIX C

Judgment of United States Court of Appeals Second Circuit

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

Docket Nos. 84-6141
84-6149

At a stated Term of the United States Court of Appeals for the Second Circuit, held at the United States Courthouse in the City of New York, on the fourteenth day of February, one thousand nine hundred and eighty-five.

Present:

HON. HENRY J. FRIENDLY
HON. THOMAS J. MESKILL
HON. LAWRENCE W. PIERCE
Circuit Judges,

GROCERY MANUFACTURERS OF AMERICA, INC., a Deleware Corporation,

Plaintiff-Appellee Cross-Appellant,

—v.—

JOSEPH GERACE, COMMISSIONER, NEW YORK DEPARTMENT OF AGRICULTURE AND MARKETS, and THE NEW YORK DEPARTMENT OF AGRICULTURE AND MARKETS,

Defendants-Appellants Cross-Appellees,

JOHN R. BLOCK, as Secretary of Agriculture of the United States and THE DEPARTMENT OF AGRICULTURE OF THE UNITED STATES MARGARET M. HECKLER, as Secretary of Health and Human Services of the United States, and THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES,

Additional Defendants on Counterclaim-Appellees.

Appendix C

Appeal from the United States District Court for the Southern District of New York.

This cause came on to be heard on the transcript of record from the United States District Court for the Southern District of New York, and was argued by counsel.

ON CONSIDERATION WHEREOF, it is now hereby ordered, adjudged, and decreed that the judgment of said District Court be and it hereby is affirmed in part and reversed in part in accordance with the opinion of this court.

ELAINE B. GOLDSMITH, Clerk

/S/ EDWARD J. GUARDARO
by EDWARD J. GUARDARO, Deputy Clerk

APPENDIX D

IN THE

UNITED STATES COURT OF APPEALS

FOR THE SECOND CIRCUIT

84-6141, 84-6149

GROCERY MANUFACTURERS OF AMERICA, INC., A Delaware Corporation,

Appellees,

v.

JOSEPH GERACE, Commissioner, NEW YORK DEPARTMENT OF AGRICULTURE AND MARKETS, and THE NEW YORK DEPARTMENT OF AGRICULTURE AND MARKETS,

Appellants,

JOHN R. BLOCK, as Secretary of Agriculture of the United States and THE DEPARTMENT OF AGRICULTURE OF THE UNITED STATES MARGARET M. HECKLER, as Secretary of Health and Human Services of the United States, and THE DEPARTMENT OF HEALTH AND HUMAN SERVICES OF THE UNITED STATES,

Appellees.

NOTICE OF APPEAL TO THE SUPREME COURT OF THE UNITED STATES

Notice is hereby given that Joseph Gerace, Commissioner, New York State Department of Agriculture and Markets and the New York Department of Agriculture and

Appendix D

Markets, the Appellants, above named, hereby appeal to the Supreme Court of The United States from the final judgment of this Court which affirmed that part of the decision of the District Court which held the labeling provisions of the New York Statute, New York Agriculture and Markets Law § 63(1) and § 63(2), and their accompanying regulations in violation of the Supremacy Clause, entered in this action on February 14, 1985.

This appeal is taken pursuant to Title 28, United States Code, Section 1254, subparagraph 2.

Dated: May 3, 1985

/s/ THOMAS G. CONWAY

THOMAS G. CONWAY, ESQ.
Attorney for Appellants,
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Certificate of Service

I hereby certify that I am a member of the bar of this court and that I have, this 3rd day of May, 1985, served a copy of this "Notice of Appeal", by first class mail, postage prepaid, upon the following:

George M. Burditt, Esquire
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Solicitor General
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Robert Abrams
Attorney General of the State of New York
Two World Trade Center
New York, New York 10047

Dated: May 3, 1985

/s/ THOMAS G. CONWAY

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APPENDIX E

N.Y. Agriculture and Markets Law

§ 63. Labeling of imitation cheese; imitation cheese food and products containing imitation cheese

1. Whenever the brand name or product designation of imitation cheese or imitation cheese food appears on a package, the brand name or product designation, whichever is larger, shall be immediately preceded, without intervening printed or graphic material by the word imitation and the name of the food imitated, in letters of the same color and on the same contrasting background and of equal size as the brand name or product designation, whichever is larger.

2. On the label of any product containing imitation cheese or imitation cheese food, the product designation shall be immediately preceded or followed by the words "contains imitation cheese" or "contains imitation cheese food" whichever is appropriate, in letters of the same color and on the same contrasting background and of equal size as the product designation.

3. Whenever imitation cheese or imitation cheese food is used in a product which is offered for sale for carry out or on premises consumption, a sign shall be prominently posted at the place of sale which states the product designation of the food followed immediately by the words "contains imitation cheese" or "contains imitation cheese food," whichever is appropriate. The letters on such sign shall be in block letters at least three inches in height and on a contrasting background which can be easily read by consumers under normal conditions of purchase.

Appendix E

4. Whenever any product which contains imitation cheese or imitation cheese food product is offered for sale on the menu of any service food establishment, the product designation on such menu shall be immediately followed by the words "contains imitation cheese" or "contains imitation cheese food", whichever is appropriate, in letters of equal size and contrasting background.

5. Whenever any imitation cheese or imitation cheese food product is placed on the tables or otherwise made available for use by customers in any service food establishment, the container of such product shall be conspicuously labeled "imitation cheese", or "imitation cheese food product".

6. The commissioner shall promulgate such rules and regulations as are necessary and appropriate to carry out the provisions of this section, including specific identification of imitation cheese and imitation cheese food.

APPENDIX F

N.Y. Regulations 1 NYCRR Part 18

LABELING AND SERVING OF IMITATION CHEESE AND IMITATION CHEESE FOOD

Sec.		Sec.	
18.1	Defintions	18.3	Notification of use of imitation cheese food in service food establishments
18.2	Labeling of cheese and imitation cheese food, and of products containing imitation cheese and imitation cheese food		

Section 18.1 Definitions. As used in this Part, unless the context otherwise requires, the following terms shall have the following meanings:

(a) *Commissioner* means the Commissioner of Agriculture and Markets of the State of New York.

(b) *Brand name* means the particular word or phrase utilized by a person who sells or offers for sale a food product, which word or phrase identifies or promotes said food product, and which distinguishes said food product from the same or a similar food product sold or offered for sale by another person.

(c) *Imitation cheese* means a food which is similar in texture, color, flavor, taste and appearance to a cheese, or a variety thereof, which is identified, described or defined in Part 17 of this Title, but does not meet a description, identity, or definition for cheese as set forth therein.

(d) *Imitation cheese food* means any food which is similar in texture, color, flavor, taste and appearance to the

food defined in sections 17.91, 17.92, 17.100, 17.101 or 17.102 of Part 17 of this Title, but does not meet the definition set forth in the appropriate section.

(e) *Label* means any portion of a package or any material affixed thereto which sets forth the brand name or product designation of the food.

(f) *Menu* means any written material which sets forth the food product sold or offered for sale.

(g) *Package* means the exterior of the container which holds the imitation cheese or the imitation cheese food, or which holds the food which contains imitation cheese or imitation cheese food.

(h) *Person* means any person, firm, corporation, copartnership, associated cooperative corporation and unincorporated association.

(i) *Product designation* means the name commonly associated with the food product which has such appearance, color, consistency, ingredients (and arrangement and mixture thereof), taste and texture.

(j) *Service food establishment* means a place where food is prepared and intended for individual portion service and includes the site at which the individual portions are provided, whether consumption occurs on the premises or off the premises after carry-out by the consumer. For the purposes of this Part, the term *service food establishment* includes, but is not limited to, restaurants, soda fountains, taverns, bars, pizzerias and any food service section in any retail food store, drug store general merchandise store.

Appendix F

18.2 Labeling of cheese and imitation cheese food, and of products containing imitation cheese and imitation cheese food. (a) No person shall sell or offer for sale imitation cheese or imitation cheese food in a package upon which the brand name or product designation of the imitation cheese or imitation cheese food appears, unless the following information is set forth upon said package in the manner forth below:

(1) Immediately preceding the brand name or product designation, whichever is larger, without intervening printed or graphic material, and on the same side or panel of the package of such food upon which the brand name or product designation appears, the words "imitation _____ cheese" or "imitation _____ cheese food" (the blanks to be filled in with the variety of the cheese imitated).

(2) The words which are required to appear, pursuant to paragrapn (1) of this subdivision, shall be prominently displayed, in letters of equal size, the same color and design, and against the same contrasting background, as the words used to indicate the brand name or product designation, whichever is larger.

(b) No person shall sell or offer for sale any product which contains imitation cheese or imitation cheese food, unless the label of the package which contains said product sets forth the following information in the manner set forth below:

(1) Immediately preceding or following the product designation without intervening printed or graphic material, and on the same side or panel of the package upon which the product designation appears, the

words "contains imitation cheese" or "contains imitation cheese food", as appropriate.

(2) The words which are required to appear, pursuant to paragraph (1) of this subdivision, shall be prominently displayed in letters of at least equal size, the same color and design, and against the same contrasting background as the product designation of the product which contains imitation cheese or imitation cheese food.

18.3 Notification of use of imitation cheese or of imitation cheese food in service establishments. (a) No person shall sell or offer for sale any product containing imitation cheese or imitation cheese food in a service food establishment, unless the menu displayed or made available therein sets forth, after the product designation or brand name, whichever is larger, of any food which contains imitation cheese or imitation cheese food, the words "contains imitation cheese" or "contains imitation cheese food", as appropriate. Said words shall (1) follow, without interruption, the product designation or brand name, as appropriate, and shall be in letters of equal size, displayed against the same contrasting background; and (2) be in letters of the same color, design and style as those in product designation or brand name, and be as easily readable as the product designation and brand name.

(b) No person shall sell or offer for sale any product containing imitation cheese or imitation cheese food in a sevrice food establishment, unless a sign which meets the following requirements is conspicuously posted therein.

Appendix F

(1) The sign shall set forth the product designation or brand name of every food sold or offered for sale therein which contains imitation cheese or imitation cheese food, immediately followed by the words "contains imitation cheese" or "contains imitation cheese food", as appropriate.

(2) The words "contains imitation cheese" and "contains imitation cheese food" shall be set forth on said sign in the same manner as the product designation or brand name and shall be against the same contrasting background. The letters of said words shall be the same height as the height of the letters in the product designation or brand name, or three inches high, whichever is larger, and of the same color, design and style thereof, and shall be easily readable as the product designation and brand name.

(3) The sign shall be plainly visible from each and every location at which a customer may place an order for food for carryout or for on-premises consumption.

APPENDIX G

Food, Drug and Cosmetic Act

21 U.S.C. § 341

Definitions and standards for food

Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: * * * *

21 U.S.C. § 342

Adulterated food

A food shall be deemed to be altered—

* * *

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value that it is.

21 U.S.C. § 343

Misbranded food

A food shall be deemed to be misbranded—

* * *

(c) Imitation of another food. If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

* * *

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401 [21 USCS § 341], unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients, other than spices, flavoring, and coloring present in such food.

21 U.S.C. § 371

Regulations and hearings

(a) Authority to promulgate regulations. The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

* * *

Appendix G

(e) Procedure for establishment. (1) Any action for the issuance, amendment, or repeal of any regulation under section 401 * * * of this Act [21 USCS §§ 341], shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirteenth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed

by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

* * *

APPENDIX H

FDA's Imitation Regulation

21 C.F.R. § 101.3(e)

Identity labeling of food in packaged form.

(e) Under the provisions of section 403(c) of the Federal Food, Drug, and Cosmetic Act, a food shall be deemed to be misbranded if it is an imitation of another food unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(1) A food shall be deemed to be an imitation and thus subject to the requirements of section 403(c) of the act if it is a substitute for and resembles another food but is nutritionally inferior to that food.

(2) A food that is a substitute for and resembles another food shall not be deemed to be an imitation provided it meets each of the following requirements:

(i) It is not nutritionally inferior to the food for which it substitutes and which it resembles.

(ii) Its label bears a common or usual name that complies with the provisions of § 102.5 of this chapter and that is not false or misleading, or in the absence of an existing common or usual name, an appropriately descriptive term that is not false or misleading. The label may, in addition, bear a fanciful name which is not false or misleading.

(3) A food for which a common or usual name is established by regulation (e.g., in a standard of identity pursuant to section 401 of the act, in a common or usual name regulation pursuant to Part 102 of this chapter, or in a regulation establishing a nutritional quality guideline pursuant to Part 104 of this chapter), and which complies with all of the applicable requirements of such regulation(s), shall not be deemed to be an imitation.

(4) Nutritional inferiority includes: (i) Any reduction in the content of an essential nutrient that is present in a measurable amount, but does not include a reduction in the caloric or fat content provided the food is labeled pursuant to the provisions of § 101.9, and provided the labeling with respect to any reduction in caloric content complies with the provisions applicable to caloric content in Part 105 of this chapter.

(ii) For the purpose of this section, a measurable amount of an essential nutrient in a food shall be considered to be 2 percent or more of the U.S. RDA of protein or any vitamin or mineral listed under § 101.9(c)(7)(iv) of this chapter per average or usual serving, or where the food is customarily not consumed directly, per average or usual portion, as established in § 101.9.

(iii) If the Commissioner concludes that a food is a substitute for and resembles another food but is inferior to the food imitated for reasons other than those set forth in this paragraph, he may propose appropriate revisions to this regulation or he may propose a separate regulation governing the particular food.

APPENDIX I

Wholesome Meat Act

21 U.S.C. § 601

Definitions

As used in this Act, except as otherwise specified, the following terms shall have the meanings stated below:

* * *

(m) The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

* * *

(8) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is;

* * *

(n) The term "misbranded" shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances:

(1) if its labeling is false or misleading in any particular;

(2) if it is offered for sale under the name of another food;

(3) if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word

"imitation" and immediately thereafter, the name of the food imitated:

* * *

(6) if any word, statement, or other information required by or under authority of this Act to appear on the label or other labeling is not prominently placed thereon with such conspiciousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) if it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by regulations of the Secretary under section 7 of this Act [21 USCS § 607] unless (A) it conforms to such definition and standard, and (B) its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

21 U.S.C. § 678

Preemption Clause

Requirements within the scope of this Act with respect to premises, facilities and operations of any establishment at which inspection is provided under title I of this Act [21 USCS §§ 601 et seq.], which are in addition to, or different than those made under this Act may not be imposed by any State or Territory or the District of Columbia, except that any such jurisdiction may impose recordkeeping and other requirements within the scope of section 202 of this Act

[21 USCS § 642], if consistent therewith, with respect to any such establishment. Marketing, labeling, packaging, or ingredient requirements in addition to, or different than, those made under this Act may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any establishment under inspection in accordance with the requirements under title I of this Act [21 USCS §§ 601 et seq.], but any State or Territory or the District of Columbia may, consistent with the requirements under this Act, exercise concurrent jurisdiction with the Secretary over articles required to be inspected under said title [21 USCS §§ 601 et seq.], for the purpose of preventing the distribution for human food purposes of any such articles which are adulterated or misbranded and are outside of such an establishment, or, in the case of imported articles which are not at such an establishment, after their entry into the United States. This Act shall not preclude any State or Territory or the District of Columbia from making requirement [requirements] or taking other action, consistent with this Act, with respect to any other matters regulated under this Act.

APPENDIX J

Poultry Products Inspection Act

21 U.S.C. § 453

Definitions

* * *

For purposes of this Act [21 USCS §§ 451 et seq.]—

* * *

(g) The term "adulterated" shall apply to any poultry product under one or more of the following circumstances:

(8) if any valuable constituent has been in whole or in part omitted or abstracted therefrom; or if any substance has been substituted, wholly or in part therefor; or if damage or inferiority has been concealed in any manner; or if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(h) The term "misbranded" shall apply to any poultry product under one or more of the following circumstances:

(1) if its labeling is false or misleading in any particular;

(2) if it is offered for sale under the name of another food;

(3) if it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the

word "imitation" and immediately thereafter, the name of the food imitated;

* * *

(6) if any word, statement, or other information required by or under authority of this Act [21 USCS §§ 451 et seq.] to appear on the label or other labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use;

(7) if it purports to be or is represented as a food for which a definition and standard of identity or composition has been prescribed by regulations of the Secretary under section 8 of this Act [21 USCS § 457] unless (A) it conforms to such definition and standard, and (B) its label bears the name of the food specified in the definition and standard and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food;

Appendix J

Poultry Products Inspection Act

21 U.S.C. § 467e

Pre-emption Clause

Requirements within the scope of this Act [21 USCS §§ 451 et seq.] with respect to premises, facilities and operations of any official establishment, which are in addition to, or different than those made under this Act [21 USCS §§ 451 et seq.] may not be imposed by any State or Territory or the District of Columbia, except that any such jurisdiction may impose recordkeeping and other requirements within the scope of paragraph (b) of section 11 of this Act [21 USCS § 460(b)], if consistent therewith, with respect to any such establishment. Marking, labeling, packaging, or ingredient requirements (or storage or handling requirements found by the Secretary to unduly interfere with the free flow of poultry products in commerce) in addition to, or different than, those made under this Act [21 USCS §§ 451 et seq.] may not be imposed by any State or Territory or the District of Columbia with respect to articles prepared at any official establishment in accordance with the requirements under this Act [21 USCS §§ 451 et seq.], but any State or Territory or the District of Columbia may, consistent with the requirements under this Act [21 USCS §§ 451 et seq.], exercise concurrent jurisdiction with the Secretary over articles required to be inspected under this Act [21 USCS §§ 451 et seq.], for the purpose of preventing the distribution for human food purposes of any articles which are adulterated or misbranded and are outside of such an establishment, or, in the case of imported articles

which are not at such an establishment, after their entry into the United States. This Act [21 USCS §§ 451 et seq.] shall not preclude any State or Territory or the District of Columbia from making requirement or taking other action, consistent with this Act [21 USCS §§ 451 et seq.], with respect to any other matters regulated under this Act [21 USCS §§ 451 et seq.].

APPENDIX K

Administrative Procedure Act

5 U.S.C. § 552

Public information; agency rules, opinions, orders, records, and proceedings

(a) Each agency shall make available to the public information as follows:

> (1) Each agency shall separately state and currently publish in the Federal Register for the guidance of the public—
>
> * * *
>
> (D) substantive rules of general applicability adopted as authorized by law, and statements of general policy or interpretations of general applicability formulated and adopted by the agency; and
>
> (E) each amendment, revision, or repeal of the foregoing.

Except to the extent that a person has actual and timely notice of the terms thereof, a person may not in any manner be required to resort to, or be adversely affected by, a matter required to be published in the Federal Register and not so published. For the purpose of this paragraph, matter reasonably available to the class of persons affected thereby is deemed published in the Federal Register when incorporated by reference therein with the approval of the Director of the Federal Register.

Appendix K

5 U.S.C. § 553

Rule making

(a) This section applies, according to the provisions thereof, except to the extent that there is involved—

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include—

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply—

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecesary, or contrary ot the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title [5 USCS §§ 556 and 557] apply instead of this susection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except—

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.